## UNITED STATES DISTRICT COURT MIDDLE DISTRICT OF TENNESSEE

| UNITED STATES OF AMERICA ex rel.                     | )                     |
|--|-----------------------|
| WJFE LLC, and on behalf of the States of CALIFORNIA, | )                     |
| COLORADO, CONNECTICUT, DELAWARE,                     | )                     |
| FLORIDA, GEORGIA, HAWAII, ILLINOIS, INDIANA,         | )                     |
| IOWA, LOUISIANA, MARYLAND, the Commonwealth          | )                     |
| of MASSACHUSETTS, MICHIGAN, MINNESOTA,               | )                     |
| MONTANA, NEVADA, NEW JERSEY, NEW MEXICO,             | )                     |
| NEW YORK, NORTH CAROLINA, OKLAHOMA,                  | )                     |
| RHODE ISLAND, TENNESSEE, TEXAS, the                  | ) No. 3:12-cv-542     |
| Commonwealth of VIRGINIA, WASHINGTON,                | ) Judge Sharp         |
| WISCONSIN and the DISTRICT OF COLUMBIA,              | ) Judge Knowles       |
|  | )                     |
| Plaintiffs,  | )                     |
| V.   | )                     |
| FERRING PHARMACEUTICALS, INC. and FERRING            | ) JURY TRIAL DEMANDED |
| INTERNATIONAL PHARMASCIENCE CENTER U.S.,             | )                     |
| INC.,  | )                     |
| Defendants.  | )                     |

## FIRST AMENDED COMPLAINT FOR FALSE CLAIMS ACT VIOLATIONS UNDER 31 U.S.C. § 3729 ET SEQ. AND STATE LAW COUNTERPARTS

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# AMENDED COMPLAINT FOR FALSE CLAIMS ACT VIOLATIONS UNDER 31 U.S.C. § 3729 ET SEQ. AND STATE LAW COUNTERPARTS

This is an action brought on behalf of the United States of America by WJFE LLC, by and through its attorneys, against Defendants Ferring Pharmaceuticals, Inc. and Ferring International PharmaScience Center U.S., Inc. (collectively, "Ferring" or Defendants), pursuant to the qui tam provisions of the Federal Civil False Claims Act (the "FCA"), 31 U.S.C. § 3729 et seq., and pursuant to the qui tam provisions of the following States: the California False Claims Act, Cal. Gov't Code § 12650 et seq. (Deering 2000); the Colorado Medicaid False Claims Act, Colo. Rev. Stat. § 25.5-4-304 et seq. (2010); the Connecticut False Claims Act for Medical Assistance Programs, Conn. Gen. Stat. § 17b-301a et seq. (2010); the Delaware False Claims and Reporting Act, Del. Code Ann. tit. 6, § 1201 et seq. (2000); the District of Columbia False Claims Act, D.C. Code § 2-308.13 et seq. (2000); the Florida False Claims Act, Fla. Stat. § 68.081 et seq. (2000); the Georgia False Medicaid Claims Act, Ga. Code Ann. § 49-4-168 et seq. (2007); the Hawaii False Claims Act, Haw. Rev. Stat. § 661-21 et seq. (2006); the Illinois False Claims Act, 740 Ill. Comp. Stat. § 175/1 et seq. (2000); the Indiana False Claims and Whistleblower Protection Act, Ind. Code § 5-11-5.5 et seq. (2007); the Iowa False Claims Act, Iowa Code § 685.1 et seq. (2010); the Louisiana Medical Assistance Programs Integrity Law, La. Rev. Stat. Ann. § 46:437.1 et seq. (2006); the Maryland False Health Claims Act of 2010, Md. Code Ann., Health-Gen. § 2-601 et seq. (LexisNexis 2010); the Massachusetts False Claims Act, Mass. Gen. Laws ch. 12, § 5A et seq. (2007); the Michigan Medicaid False Claims Act, Mich. Comp. Laws § 400.601 et seq. (2007); the Minnesota False Claims Act, Minn. Stat. § 15C.01 et seq. (2011); the Montana False Claims Act, Mont. Code Ann. § 17-8-401 et seq. (1999); the Nevada False Claims Act, Nev. Rev. Stat. § 357.010 et seq. (2007); the New Jersey False Claims Act, N.J. Stat. Ann. § 2A:32C-1 et seq. (West 2007); the New Mexico Medicaid False Claims

Act, N.M. Stat. Ann. § 27-14-1 et seq. (2007); the New York False Claims Act, N.Y. State Fin. Law § 187 et seq. (McKinney 2010); the North Carolina False Claims Act, N.C. Gen. Stat. § 1-605 et seq. (2010); the Oklahoma Medicaid False Claims Act, Okla. Stat. tit. 63, § 5053 et seq. (2007); the Rhode Island False Claims Act, R.I. Gen. Laws § 9-1.1-1 et seq. (2008); the Tennessee Medicaid False Claims Act, Tenn. Code Ann. § 71-5-181 et seq. (2006); the Texas Medicaid Fraud Prevention Act, Tex. Hum. Res. Code Ann. § 36.001 et seq. (West 2006); the Virginia Fraud Against Taxpayers Act, Va. Code Ann. § 8.01-216.1 et seq. (2011); the Washington Medicaid False Claims Act, S. 5978, 62nd Cong. § 201 et seq. (2012); and the Wisconsin False Claims for Medical Assistance Law, Wis. Stat. § 20.931 et seq. (2007) ("State qui tam statutes" or "Qui Tam States").

#### I. STATEMENT OF THE CASE

- 1. This is an action to recover damages and civil penalties on behalf of the United States and the *Qui Tam* States arising from false and/or fraudulent records, statements and claims made, used or presented, and/or caused to be made, used or presented by Defendants and/or their agents, employees or co-conspirators under the Federal False Claims Act and the State *qui tam* statutes.
- 2. Defendants are companies and individuals that manufacture, market, and sell a variety of drugs and devices for medicinal purposes. Beginning at least in 2010, Defendants have engaged in a variety of fraudulent activities involving their osteoarthritis device Euflexxa. Euflexxa is an ultra-high purity hyaluronan, also called hyaluronic acid ("HA") or sodium hyaluronate. Euflexxa, a medical device, was first approved by the Food and Drug Administration ("FDA") in 2004 for the treatment of pain in osteoarthritis of the knee in patients

who have failed to respond adequately to conservative non-pharmacologic therapy and simple analysics (e.g., acetaminophen).

- 3. Defendants have, as part of their fraudulent scheme, engaged in certain illegal conduct involving the marketing of Euflexxa, including: (i) providing illegal kickbacks; (ii) violating Government pricing rules by offering private payors more favorable prices and terms than Defendants charge Government payors; and (iii) making false "superiority" claims as to its competitors without any scientific basis for such claims.
- 4. As part of its Fraudulent Kickback Scheme, Ferring directed its sales representatives to use free, trade-size samples of its Euflexxa syringes as an incentive to persuade healthcare providers either to switch their patients to Euflexxa from competing brands (e.g., Hyalgan and Supartz) or, for current customers, to continue prescribing Euflexxa. The Company also instructed its sales representatives to encourage healthcare providers to illegally bill for use of the free, trade-size samples. In some instances, the providers actually sought such reimbursement for use of the free product, including from federal programs like Medicare and Medicaid. To further the fraud, the Company itself sent the free samples directly to the physicians to ensure the scheme was effectively carried out and that the inducements were properly received.
- 5. To further the Fraudulent Kickback Scheme, Ferring also directed its sales representatives to take advantage of the fact that Euflexxa is a "buy and bill" injectable device, and specifically promote it to physicians as a separate and distinct means of generating income. Ferring recognized the revenue stream available to its customers and encouraged its representatives to "market the spread"— *i.e.*, the difference between the reimbursement rate paid by the Federal Health Care Programs and the actual purchase price paid by health care providers.

The larger the "spread" on a drug or device, the larger the profit or "return on investment" for the provider.

- 6. As an additional part of its Fraudulent Kickback Scheme, Ferring adopted a sales model that incentivized physicians to prescribe Euflexxa by rewarding them with lucrative speaking engagements, charitable contributions and free lunches as an illegal *quid pro quo*. In addition, Ferring offered illegal remuneration to its physician customers in the form of free reimbursement and referral services to induce physicians to prescribe Euflexxa.
- 7. Ferring also deployed a Fraudulent Marketing Scheme in which the Company instructed its sales force to promote Euflexxa's "superiority" as the safest and most efficacious choice among HA products, despite having no substantial evidence providing support for such claims. Ferring based its superiority claims on at least three specific characteristics of the device, namely that: (i) Euflexxa is the first FDA-approved HA product that is not derived from avian sources (i.e., chicken or rooster combs) and, because it is produced from "bioengineered bacteria," it is therefore more "pure" than its competitors' HA products; (ii) its "biorestorative" features most resemble naturally-occurring, endogenous HA, thus making it the superior HA product; and (iii) Euflexxa's higher molecular weight provides an improved clinical benefit as compared to competing products of lower weights. None of these claims, however, is supported by any adequate, well-controlled studies in which the products were compared head-to-head using comparable dosage regimens or by a single, large, well-controlled study. Despite the lack of evidence supporting these superiority claims, Ferring nevertheless instructed its sales personnel to use these superiority claims to persuade healthcare professionals to prescribe Euflexxa in lieu of the other HA products and in violation of the applicable laws and regulations.

- 8. In reliance on Ferring's published policies for reporting illegal activity, Relator initially contacted the Company's compliance department in an effort to alert them to the illegal conduct associated with the sale and marketing of Euflexxa. Based on the information Relator brought to the Company's attention, Ferring immediately initiated an internal investigation. Ferring's investigation ultimately confirmed Relator's allegations. The Company further acknowledged to Relator that, while the Company understood that he had not participated in any of the wrongdoing, the illegal promotional practices Relator had observed were company-wide in nature.
- 9. Rather than expressing gratitude to Relator for coming forward and internally reporting the illegal conduct, Ferring terminated Relator in direct retaliation for his whistleblowing activities. Ferring's retaliation was, not coincidentally, merely one month after Relator initially reported the illegal conduct and less than a week after the Company completed its investigation. Ferring's wrongful termination of Relator—particularly in light of the fact that Relator had not taken part in any of the illegal promotional activities—was made in violation of the False Claims Act's prohibition against such retaliation. *See* 31 U.S.C. § 3730(h).
- 10. Ferring's illegal promotion of Euflexxa has caused numerous false claims to be submitted to federal and state healthcare programs throughout the United States. Ferring's misconduct cheated the federal and state governments out of monies that should not have been paid, thereby illegally enriching the Company at taxpayer expense, and subjecting patients to unapproved, ineffective and unsafe uses of Euflexxa.
- 11. Also, by systematically providing physicians with large numbers of free samples of Euflexxa for the purpose of inducing physicians to buy Euflexxa and bill Federal health care programs—including Medicare and Medicaid—for such samples, Ferring violated the

Prescription Drug Marketing Act 21 U.S.C. §§ 353, et seq., (the "PDMA"), which governs the distribution of drug samples, as well as Federal and State "best price" statutes and regulations, which require that such free samples of product, offered for the purpose of inducing purchases, be included in the calculation of the most favorable prices offered to customers.

- 12. At all relevant times, Ferring has known that Euflexxa is being paid for or reimbursed by Government Programs, including Medicaid and Medicare Part B.
- 13. Defendants knew, or reasonably should have known, that their conduct described herein would lead to the submission of claims for reimbursement by Government Programs that were not eligible for reimbursement. But for Defendants' illegal conduct, those prescriptions would not have been written. As a result, Defendants have caused, and continue to cause, the submission of false claims to Government Programs, and they have benefited from the payment of those false claims.
- 14. For example, and as described more fully herein, Dr. Randall Peyton, an orthopedic surgeon located in Sterling, Virginia, received various forms of unlawful remuneration by Ferring, including speaker fees and free samples of Euflexxa. As a direct and intended result of Ferring's kickback scheme, Dr. Peyton became one of the top purchasers/subscribers of Euflexxa in the country. In 2012 alone, he billed Medicare for nearly 1,000 doses of Euflexxa, for which he sought \$219,120.00 in government reimbursements. As described herein, and as illustrated in the attached Exhibit A, many doctors and medical practices targeted by Ferring's sales force, and personally known to Relator, billed Medicare for Euflexxa treatments, and received sizable reimbursements as the result of these false claims. The specific examples of Euflexxa Medicare claims in Exhibit A are representative of the thousands of instances in which Ferring has provided free samples to health care professionals as kickbacks

for prescribing Euflexxa to Government Program beneficiaries, and which has resulted in the submission of false claims for Euflexxa to those Government Programs.

#### II. JURISDICTION AND VENUE

- 15. This Court has subject matter jurisdiction over this action pursuant to 31 U.S.C. § 3732(a) and 28 U.S.C. §§ 1331 and 1345. The Court has original jurisdiction of the State law claims pursuant to 31 U.S.C. § 3732(b) because this action is brought under State laws for the recovery of funds paid by the *Qui Tam* States, and arises from the same transaction or occurrence brought on behalf of the United States under 31 U.S.C. § 3730.
- 16. This Court has personal jurisdiction over the Defendants because, among other things, the Defendants transact business in this judicial district, and engaged in wrongdoing in this judicial district.
- 17. Venue is proper in this judicial district under 31 U.S.C. § 3732(a) and 28 U.S.C. §§ 1391(b) and (c). The Defendants transact business within this judicial district, and acts proscribed by 31 U.S.C. § 3729 occurred in this judicial district.
- 18. The causes of action alleged herein are timely brought because, among other things, Defendants have taken steps to conceal from the United States their wrongdoing in connection with the allegations made herein.

#### III. PARTIES

#### A. PLAINTIFF/RELATOR WJFE LLC

19. Plaintiff/Relator WJFE LLC, a Delaware limited liability company, brings this action on behalf of itself, the United States of America and the *Qui Tam* States named herein. Its principal place of business is c/o Seeger Weiss LLP, 77 Water Street, New York, NY 10005. Among the members of WJPE LLC is a current or former Ferring employee (referred to herein

as "Relator") with personal knowledge of the fraudulent scheme alleged in this Complaint. Relator possesses personal knowledge and experience regarding Ferring's sales promotion activities, including personal contact with the employees and executives of Ferring who have committed the violations of law alleged herein. The personal knowledge of WJFE LLC is not distinct from that of the Relator.

- 20. Relator had personal knowledge and experience regarding Ferring's sales promotion activities, including personal contact with the employees and executives who have committed violations of law alleged herein. Relator also observed numerous instances of illegal conduct at Ferring, including "marketing the spread" (resulting in Ferring falsely reporting its Average Sales Price) and providing illegal kickbacks to healthcare providers in exchange for their agreements to purchase and then prescribe Euflexxa.
- 21. Prior to filing this Amended Complaint, Relator brought allegations of wrongdoing to the attention of Ferring by raising these concerns with various supervisors, including Jean Frydman, Ferring's Chief Compliance Officer at the time. Less than a month later, as a direct result of Relator's internal reporting, Ferring terminated his employment. As a pretext for his firing, Ferring offered only that Relator had allegedly engaged in insubordination for not coordinating travel plans necessary to attend a technology training meeting at the Company's corporate headquarters in New Jersey—a meeting that Ferring had previously and explicitly instructed him not to attend.
- 22. Relator is an original source of the allegations in this Amended Complaint, and these allegations are not based upon publicly-disclosed information. Relator previously provided the Government with material information prior to the filing of his original Complaint in accordance with 31 U.S.C. § 3730(b)(2), including hundreds of pages of documents and a

preliminary disclosure statement. Relator timely and properly served the United States and the *Qui Tam* States with the disclosure statement, disclosure materials, and the original Complaint.

#### B. DEFENDANT FERRING

- 23. Defendants Ferring Pharmaceuticals, Inc. and Ferring International PharmaScience Center U.S., Inc. (collectively, "Ferring") are Delaware limited liability companies with headquarters and research facilities located at 4 Gatehall Drive, Parsippany, New Jersey 07054.
- As described more fully herein, Ferring is engaged in the manufacture, promotion, distribution, commercialization, and sale of prescription products. At all times material hereto, Ferring marketed and sold a range of brand pharmaceuticals, medical devices, and consumer medicines, including Euflexxa, throughout the United States, including within this judicial district.
- 25. Ferring markets and sells, and marketed and sold, brand-name prescription drug and medical device products, including Euflexxa, that are paid or reimbursed by various government programs, including health benefit carriers offering benefits under the Federal Employees Health Benefits ("FEHB") program under a prime contract with the Blue Cross Blue Association ("BCBSA"), the Health Insurance Program for the Elderly and Disabled, more commonly referred to as the Medicare Program, 42 U.S.C. § 1395 *et seq.*, via Medicare Part C, (also known as Medicare+Choice), Medicare Part B, Medicare Advantage, the Indian Health Service, Medicaid, the Mail Handler's Health Benefit Plan ("MHHBP"), the U.S. Secret Service Employees Health Association ("SSEH") Health Benefit Plan, the Civilian Health and Medical Program of the Uniformed Services ("CHAMPUS," now known as "TRICARE") and the Veterans Health Administration ("VHA") (collectively, the "Government Programs").

26. As a result of Ferring's actions, the *Qui Tam* States and Government Programs have suffered significant financial harm.

#### IV. SUMMARY OF DEFENDANTS' ILLEGAL CONDUCT

### A. THE FRAUDULENT KICKBACK SCHEME

27. It was the plan and purpose of Ferring's Fraudulent Kickback Scheme to: (i) provide free "samples" of Euflexxa to physicians in exchange for inducing their commitment to purchase quantities of Euflexxa; (ii) induce physicians to purchase and then prescribe Euflexxa in lieu of other HA products based on the "spread" between what they would pay to purchase the product, and what they would be paid in the way of "free" services and kickbacks to prescribe it; and (iii) use speaker programs and other monetary incentives to encourage and reward high-prescribing "key opinion leaders" to prescribe Euflexxa (hereinafter, the "Fraudulent Kickback Scheme"). These actions violated the Federal Anti-Kickback Statute ("AKS"), 42 U.S.C. § 1320a-7b(b), because they were taken knowingly to induce customers to buy Euflexxa and then prescribe Euflexxa instead of cheaper and potentially more suitable alternatives.

28. The exchange of free samples and services for agreements to purchase quantities of Euflexxa also violates the Code of Ethics on Interactions with Health Care Professionals as set forth by the Advanced Medical Technology Association ("AdvaMed")—the leading medical device trade association in the United States. The AdvaMed Code of Ethics prohibits the sale, purchase, or trade of drug devices, including biological products that are also medical devices, such as Euflexxa.

- 29. These kickbacks were intended to result in the dispensing of Euflexxa, and subsequent reimbursement by Ferring's customers, including its Government Program customers instead of cheaper and potentially more suitable alternatives.
- 30. In fact, Ferring instructed its sales representatives to encourage healthcare providers to illegally bill for use of the free, trade-size samples. And those healthcare providers, in many instances, did seek reimbursement from Federal Programs, including Medicare and Medicaid.
- 31. The payment and receipt of these kickbacks resulted in increased expense to Government Program customers insofar as physicians would have, in the absence of Ferring's kickback, prescribed cheaper products or no product at all.
- 32. Ferring's provision of free Euflexxa samples and services to its customers was made knowingly and with the intent to cause claims to be submitted to Government Programs for payment for Euflexxa through a pattern of corrupt and illegal conduct.
- 33. Ferring also made quid pro quo payments in the form of speaker fees and other inducements in exchange for physicians' continued loyalty to Euflexxa.
- 34. Moreover, Ferring's kickbacks caused physicians and others submitting claims to the Government to falsely certify compliance with applicable laws and regulations, including that the claims were not tainted by illegal kickbacks.
- 35. Ferring's conduct underlying the Fraudulent Kickback Scheme was made in violation of the AKS, the Federal Acquisition Regulations System ("FARS"), and the Federal and state False Claims Acts.

#### B. THE FRAUDULENT MARKETING SCHEME

- 36. It was the plan and purpose of the Defendants' fraudulent marketing scheme to illegally promote Euflexxa by making false "superiority" claims over competing hyaluronic acid ("HA") products (hereinafter, the "Fraudulent Marketing Scheme"). The objective of the Fraudulent Marketing Scheme was to increase sales of Euflexxa.
- Specifically, Ferring sales representatives were instructed to (and did) tout Euflexxa's position as the first FDA-approved HA product that is not derived from avian sources (i.e., chicken or rooster combs) and, therefore, is more "pure" than its competitors' products and thus, according to Ferring, would cause fewer adverse reactions. The Company also touted completely unfounded "biorestorative" features of Euflexxa, claiming that this makes the device "superior" to the other HA products. Ferring also trained its sales force to promote Euflexxa based on the theory that its higher molecular weight—as compared to the lower molecular weight of competing HA products—provides superior clinical benefit. Importantly, however, none of these claims is supported by adequate clinical evidence concluding that any of these characteristics equate to any clinical benefit to the patient.
- 38. These unsubstantiated, comparative claims are prohibited by the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 352 and 21 C.F.R. § 202.1(e)(6), as well as Ferring's own internal sales policies. The use of unsubstantiated comparative claims renders a medical device "misbranded" by the FDA. Ferring promoted these Euflexxa falsehoods to physicians to induce physicians to purchase and then prescribe Euflexxa. Once Euflexxa became "misbranded" it was no longer eligible for reimbursement by Federal Programs, including Medicare and Medicaid.
- 39. In fact, a report issued by the Veterans Affairs Pharmacy Benefits Management Services concluded that there is **no** evidence to support a claim that one HA product has an

efficacy advantage over any other. *See* Viscosupplementation for Osteoarthritis of the Knee: Intra-Articular Administration of Hyaluronan (Hyaluronic Acid) and Hylan G-F 20 Products; VHA Pharmacy Benefits Management Services and the Medical Advisory Panel, *available at* http://www.index.va.gov/search/va/va\_search.jsp?SQ=&TT=1&QT=hyaluron (last visited April 9, 2012). The report also found that there does not appear to be any safety difference between the HA products. *Id.* (noting that there may be some unique, but rare, safety concerns related to use of Synvisc®, including case reports of pseudosepsis or severe acute inflammatory reactions and at least a few reporting granulomatous inflammation).

- 40. Ferring was required to provide fair and balanced information whenever it engaged in promotional activities. Fair and balanced promotional activities include written materials as well as oral presentations. According to federal regulations and industry standards and practices, "fair and balanced" means that whenever Ferring made representations about Euflexxa's efficacy, it was required to also make statements about the device's side effects.
- 41. In violation of federal law, Ferring knowingly and deliberately failed to give fair and balanced presentations on Euflexxa. These false superiority claims about Euflexxa's efficacy were made without "substantial evidence" to support such claims. As such, any statements about Euflexxa's efficacy were false, misleading, distorted, inaccurate, unfair, imbalanced and omitted material facts Ferring was required to disclose.
- 42. Defendants intended that their Fraudulent Marketing Scheme would cause false and fraudulent statements and/or claims for payment to be submitted to Government Programs. That is what occurred, permitting Defendants to maximize profits through ill-gotten gains.
- 43. The Fraudulent Marketing Scheme was designed and deployed in violation of the Federal False Claims Act, 31 U.S.C. § 3729 *et seq.*, and its state analogues.

- 44. Defendants' unlawful promotion of Euflexxa involved the unlawful making of false records or statements and/or causing false claims to be submitted for the purpose of getting the false records or statements to bring about the Federal Government and *Qui Tam* States' payment of false or fraudulent claims.
- 45. Defendants' conduct had a material effect on the Federal Government and *Qui Tam* States' decision to pay for Euflexxa. Had the Federal Government and *Qui Tam* States known that the prescriptions were the direct and intended result of Defendants' unlawful activities, they would not have made such reimbursements.
- 46. It further was part of the Fraudulent Marketing Scheme that Defendants attempted to conceal and cover up the illegal marketing of Euflexxa.
  - 47. The Fraudulent Marketing Scheme is ongoing.

#### C. THE BEST PRICE SCHEME

- 48. Ferring's scheme to provide free Euflexxa samples to induce the purchase of its product implicates the Best Price provisions of the Federal Acquisition Regulations System ("FARS"). Pursuant to the FARS, "[t]he Government will seek to obtain the offeror's best price (the best price given to the most favored customer)." *See* 48 C.F.R. § 538.270(a). The calculation of Best Price must include, *inter alia*, "[f]ree goods" the provision of which are "not contingent upon any purchase requirement." *See* 48 C.F.R. § 447.505 (d)(10).
- 49. Ferring was aware of the FARS, and knew that its compliance with those regulations was required, but nonetheless violated those regulations.
- 50. When Ferring provides free samples of Euflexxa to its customers in an effort to induce them to prescribe more of the product, the Company is required to account for the value of the free samples when it calculates its Best Price, because the provision of these free samples

is "contingent upon [a] purchase requirement." See 48 C.F.R. § 447.505 (d)(10). The Company has failed to do so.

- 51. The impact of even one such "free" sample in any quarter would, by implication, create a Best Price of \$0 per syringe, compared to the approximately \$135 per syringe that Ferring would have reported.
- 52. In addition, Relator became aware that Ferring offered Euflexxa to physicians at prices well below those offered to Government customers, including the Veterans Health Administration. Specifically, Relator knew that Ferring gave pricing discounts for Euflexxa to Commonwealth Orthopaedics in Alexandria, Virginia, that Ferring did not make available to hospitals serving Veterans Health Administration beneficiaries.
- 53. Because Ferring intentionally failed to account for these discounts in its pricing for Euflexxa, the Company wrongfully over-charged Government customers, including the Veterans Health Administration, for its product, and it retained such overpayments. Ferring's sales to the Veterans Health Administration and other Government payors that violate the FARS each constitute false claims prohibited by the FCA.
- 54. Ferring knowingly (or with reckless disregard for the truth) made, used, or caused to be made or used, false records or statements to get false or fraudulent claims paid or approved by the Government. Specifically, for the period noted above, and continuing through the present, Ferring knowingly (or in reckless disregard for the truth) failed to offer its Government customers with the Best Price for Euflexxa.
- 55. By virtue of the acts described below, Ferring provided discounts to and through physicians that constituted a Best Price, which Ferring did not report to the government as required by the Medicaid Best Price statute.

56. Ferring's false calculation of its Euflexxa Best Price caused Government customers to pay inflated amounts in violation of the FARS.

## V. BACKGROUND OF THE REGULATORY FRAMEWORK

## A. THE FOOD AND DRUG ADMINISTRATION'S ("FDA") ROLE IN REGULATING MEDICAL DEVICES

- 57. The Food and Drug Administration ("FDA") is an agency of the United States responsible for protecting the health and safety of the public by assuring, among other things, that medical devices intended for use in the treatment of humans are safe and effective for their intended uses and that the labeling of such devices bear true and accurate information. Pursuant to this statutory mandate, the FDA regulates the manufacture, labeling, and shipment in interstate commerce of any such devices.
- 58. Under the Federal Food, Drug and Cosmetic Act ("FDCA"), 21 U.S.C. §§ 301-397, and pursuant to Title 21 of the United States Code, Section 321(h), the term "device" includes "an . . . implant . . . or other similar or related article . . . which is . . . intended for use in . . . the treatment or prevention of disease of man . . . or intended to affect the structure or any function of the body of man . . . which does not achieve its primary intended purposes through chemical action within or on the body of man and which is not dependent upon being metabolized for the achievement of its primary intended purposes."
- 59. Pursuant to the FDCA, every manufacturer of a new device is required to obtain "clearance" or "approval" from the FDA prior to marketing its device.
- 60. All devices marketed in interstate commerce in the United States fall into one of three regulatory classes under the FDCA. The Class assigned reflects the FDA's perception of the level of risk presented by the device and the degree of regulatory control necessary to provide reasonable assurance of the safety and effectiveness of that device for its intended use. Class III

devices are subject to the most stringent regulatory requirements; Class I devices to the least stringent requirements.

- 61. Class I devices and certain Class II devices are exempt from pre-market review. Most Class II devices and certain Class III devices are marketed after submission of a pre-market notification under a process that is known as a 510(k) notification procedure.
- 62. Most Class III devices and devices not substantially equivalent to a predicate device are subject to the most stringent regulatory review and cannot be marketed for commercial sale in the United States until the manufacturer has submitted a pre-market approval ("PMA") application to the FDA and the FDA has approved that application. The FDA will not grant pre-market approval unless the information in the PMA application provides the FDA with reasonable assurance that the device is safe and effective when used according to its labeling. The PMA filing is subject to a substantial user fee payment. PMA supplement applications are also subject to user fees.
- 63. A PMA must contain proposed directions for use of the device, information about the manufacturing processes and facilities, technical information and reports of non-clinical laboratory studies of the device, clinical data demonstrating that the device is safe and effective for its intended use, certain information regarding pediatric subpopulations, and other information required by the FDA.
- 64. As part of the pre-market approval or clearance process, the FDA often requires device manufacturers to submit the results of clinical trials or investigations—that is, testing on human subjects. Manufacturers of significant risk devices (a "significant risk" device is an implant or other device that presents a potential for serious risk to the health, safety or welfare of a human subject) cannot legally conduct clinical trials or investigations (a "clinical trial" or

"clinical investigation" is an investigation or research involving one or more human subjects to determine the safety or effectiveness of a device) in the United States without first obtaining the FDA's permission to do so, by way of an Investigational Device Exemption ("IDE"). Before beginning a clinical trial of a significant risk device, the device manufacturer is required to obtain the FDA's approval of the IDE. Additionally, a multi-disciplinary group of professionals with backgrounds in areas such as science, medicine, and bioethics, called an Institutional Review Board ("IRB"), is required to approve the investigational plan and informed consent form so that the clinical trial is properly monitored and the human subjects properly protected. In some limited circumstances, an IDE does not need to be filed if the manufacturer is conducting consumer preference testing of the device, but only if the testing is not for the purpose of determining safety or effectiveness and does not put subjects at risk. The requirements of an IDE to permit clinical trials, and an IRB to oversee clinical trials, combined with the expense of planning and carrying out clinical trials, mean that obtaining pre-market approval from the FDA for a significant risk device often is a long and expensive process.

- 65. If the FDA's evaluation of a PMA is favorable, the FDA typically issues an "approvable letter" requiring the applicant to agree to comply with specific conditions, to supply specific additional data or information, or to finalize the labeling, in order to secure final approval of the PMA application. Once the conditions contained in the approvable letter are satisfied, the FDA will issue a PMA order for the approved indications, which can be more limited than those originally sought by the manufacturer.
- 66. On December 3, 2004, the Center for Devices and Radiological Health ("CDRH"), which is responsible for regulating firms who manufacture, repackage, relabel, and/or import medical devices sold in the United States, granted Savient Pharmaceuticals' PMA

for Nuflexxa (1% sodium hyaluronate) for the treatment of pain in osteoarthritis of the knee in patients who have failed to respond adequately to conservative non-pharmacologic therapy and to simple analgesics (*e.g.*, acetaminophen). In July 2005, Ferring purchased Savient's global biologics manufacturing business, including the rights to market Nuflexxa (later changed to Euflexxa) in the United States. Subsequently, Euflexxa, which was approved as a Class III device, became available to the public on November 8, 2005.

- 67. The device manufacturer's application to the FDA is required to contain proposed labels and labeling sufficient to describe the device, its intended use, and the directions for its use. A device is cleared or approved by the FDA on the basis of its intended use, and the FDA approved use is required to be included in the device's labeling.
- 68. Medical device advertising and promotion are subject to federal and state regulations. In the United States, the FDA regulates company and product promotion, including direct-to-consumer advertising. Violative materials may lead to FDA enforcement action, including the imposition of civil monetary penalties utilizing new authority the FDA has been granted.
- 69. Under the Medicare Benefit Policy Manual, medical devices that may be covered under Medicare include devices approved by the FDA through the PMA process. Thus, to the extent that a medical device is being used beyond its approved PMA, it would not be covered by Medicare.
- 70. As a result of its having promoted Euflexxa beyond its FDA-approved label by means of using unfounded "superiority" claims, Ferring caused false statements, false or fraudulent claims, and/or false certifications of compliance to have been submitted. Thus,

Ferring wrongfully obtained millions of dollars from Medicare, Medicaid, and TRICARE/CHAMPUS to which it was not entitled.

#### B. THE PRESCRIPTION DRUG MARKETING ACT

- 71. Prescription Drug Marketing Act 21 U.S.C. §§ 353, *et seq.*, (the "PDMA"), governs the distribution of drug samples.
- The PDMA permits sales representatives to distribute drug samples to licensed physicians, but only upon the signed written request from the licensed physician for the drug samples. 21 U.S.C. § 353(d)(3)(A); 21 C.F.R. § 203.31. Such written requests, which have to be received before the drug samples are delivered, must, *inter alia*, identify (a) the physician, (b) the quantity of the particular drug samples requested, and (c) the date of the request. 21 U.S.C. § 353(d)(3)(A); 21 C.F.R. § 203.31(a)(1) and (b).
- 73. Manufacturers or authorized distributors of record shall not distribute drug samples on the basis of open-ended or standing requests, but shall require separate written requests for each drug sample or group of samples." 21 C.F.R. § 203.35.
- Physicians are required to sign receipts for all drug samples received from sales representatives. 21 C.F.R. § 203.31(a)(3) and (c). Such receipts must, *inter alia*, identify (a) the physician or the physician's designee who acknowledges the delivery of the drug samples, (b) the quantity of the particular drug samples delivered, and (c) the date of the delivery. 21 C.F.R. § 203.31(c)(1).
- 75. Pursuant to the PDMA, Ferring is required, *inter alia*, to maintain detailed records of (a) all inventories of drug samples, (b) all drug samples distributed to physicians, (c) all sales representatives who distributed drug samples to physicians, and (d) all of the written requests for drug samples made by physicians. 21 U.S.C. § 353(d)(3)(C); 21 C.F.R. § 203.31(d) and (e).

76. PDMA mandates that "[n]o person may sell, purchase, or trade or offer to sell, purchase, or trade any drug sample." 21 U.S.C. § 353(c)(1).

### C. FEDERAL HEALTH CARE PROGRAMS AND OTHER GOVERNMENT PROGRAMS

## 1. The Medicaid Program

- 77. Medicaid is a public assistance program providing for payment of medical expenses for approximately 55 million low-income patients. Funding for Medicaid is shared between the Federal Government and state governments. The Medicaid program subsidizes the purchase of more prescription drugs and devices than any other program in the United States.
- 78. Although Medicaid is administered on a state-by-state basis, the state programs adhere to federal guidelines. Federal statutes and regulations restrict the devices and device uses that the Federal Government will pay for through its funding of state Medicaid programs.

## 2. The Medicare Program

- 79. The Medicare Program ("Medicare") is a federal program that provides free or below-cost health care benefits to certain individuals, primarily the elderly, blind, and disabled. Medicare is a "health care benefit program" as defined by Title 18 of the United States Code, Section 24(b).
- 80. Individuals who receive benefits under Medicare are commonly referred to as "beneficiaries." The Medicare Part B program is a federally-funded supplemental insurance program that provides supplementary Medicare insurance benefits for individuals aged sixty-five or older and certain individuals who are disabled. The Medicare Part B program pays for medical services, including devices, for beneficiaries.
- 81. According to the CMS Medicare Benefit Policy Manual, Medicare "may cover certain FDA-approved . . . devices and services incident to" those devices. More specifically,

devices that may be covered under Medicare include the following categories: (i) devices approved by the FDA through the Pre-Market Approval (PMA) process; (ii) devices cleared by the FDA through the 510(k) process; (iii) FDA-approved IDE Category B devices; and (iv) hospital Institutional Review Board (IRB) approved IDE devices.

## 3. Reimbursement Under Other Federal Health Care Programs

- 82. In addition to Medicaid and Medicare, the Federal Government reimburses a portion of the cost of prescription devices under several other federal health care programs. For example:
  - (i) CHAMPUS/TRICARE is a health care program administered by the Department of Defense for individuals and dependants affiliated with the armed forces.
  - (ii) CHAMPVA is a health care program administered by the Department of Veterans Affairs for families of veterans with 100% service-connected disabilities.
  - (iii) The Federal Employee Health Benefit Program provides health insurance for federal employees, retirees and survivors, and it is administered by the Office of Personnel Management.

Coverage of device use under these programs is similar to the coverage provided by the Medicaid program. *See*, *e.g.*, TRICARE Policy Manual 6010.47-M, Chapter 7, Section 7.1 (B)(2) (March 15, 2002); CHAMPVA Policy Manual, Chapter 2, Section 22.1, Art. II (A)(2) (June 6, 2002).

83. When a healthcare provider seeks reimbursement from Medicare, it first identifies the particular reimbursement code for the drug or device prescribed. These reimbursement codes are a component of the CMS Healthcare Common Procedure Coding System ("HCPCS"). The HCPCS is designed to bill for drugs and devices that are utilized in the physician's office, clinic or home health agency. Under this classification scheme, most covered drugs and devices are

assigned J-codes, which are permanent codes used to identify injectable drugs and devices that ordinarily cannot be self-administered, as well as some oral anti-cancer drugs. The J-Code for Euflexxa is J7323.

- 84. Euflexxa can also be dispensed at pharmacies for patients with a prescription. Pharmacies seek reimbursement from Medicare based on a device's National Drug Code ("NDC") number. The NDC code for a 2.25 mL nominal volume, disposable, pre-filled glass syringe containing 2 mL of Euflexxa is 55566-4100-1.
- 85. Under Federal health care programs, such as Medicare and Medicaid, physicians are reimbursed not only for the cost of Euflexxa, but also for their services in administering Euflexxa. As Defendants have further advised physicians, °'[i]f another professional service is provided during the same visit, the physician may be able to charge for an office visit as well.

## D. FERRING ADOPTS PHRMA AND ADVAMED CODES ON GIFTS TO HEALTH CARE PROFESSIONALS

86. In 2002, the Pharmaceutical Research and Manufacturers of America ("PhRMA") adopted its Interactions with Health Care Professionals, or the "PhRMA Code," as updated in July 2008 and effective in January 2009. The PhRMA Code seeks to promote transparency in relationships between health care professionals and the pharmaceutical industry and to ensure that pharmaceutical marketing activities comport with the highest ethical standards. The most recent revisions to the PhRMA Code, effective January 2009, restrict or prohibit many activities previously permissible under the prior PhRMA Code, including: a prohibition on any entertainment or recreational events for non-employee health care professionals, including strict limitations on meals with physicians; the elimination of non-educational business gifts; restrictions on speaker programs; and clarifications on continuing medical education funding. The updated PhRMA Code also requires that pharmaceutical companies train their sales

representatives on all applicable laws, regulations, and industry codes governing interactions with health care professionals. Complying with the PhRMA Code is not a guarantee that a company is in compliance with the law.

- 87. In addition, the Advanced Medical Technology Association's Revised Code of Ethics, or the "AdvaMed Code," also seeks to ensure that medical device companies and health care professionals have collaborative relationships that meet high ethical standards; medical decisions are based on the best interests of patients; and medical device companies and health care professionals comply with applicable laws, regulations and government guidance. The AdvaMed Code was updated in December 2008 and became effective in July 2009. The revisions generally follow the 2008 changes in the PhRMA Code and include limitations on consulting arrangements, entertainment, and meals and gifts, among others. Complying with the AdvaMed Code is not a guarantee that a company is in compliance with the law.
- 88. Ferring announces on its website that "[a]ll interactions with healthcare professionals should be guided by:
  - Compliance Code for US-based employees of Ferring Pharmaceuticals, provided in orientation materials;
  - Marketing & Sales policies;
  - Field Guide on Healthcare Law Compliance;
  - PhRMA Code on Interaction with healthcare professionals;
  - AdvaMed Code on Interaction with healthcare professionals;
  - Applicable national and regional industry association codes; and
  - Applicable laws, regulations, and other industry standards.
- 89. Yet, despite the statement that the Company would ostensibly adopt and implement a compliance program which it believes satisfies the requirements of these laws, regulations, and the PhRMA and AdvaMed codes, as set forth herein, it has nonetheless concealed its widespread violations of even its own compliance program in its marketing of its products to health care professionals.

### VI. BACKGROUND ON EUFLEXXA

- 90. Euflexxa is an injected formulation of sodium hyaluronate, which is similar to the fluid that generally surrounds the joints and functions as a lubricant and "shock absorber" for the knee. Since 2005, Euflexxa has been exclusively marketed and sold in the United States by Ferring.
- 91. Euflexxa was first approved by the FDA on December 3, 2004 for treatment of pain in osteoarthritis of the knee in patients who have failed to respond adequately to conservative non-pharmacologic therapy and simple analgesics (e.g., acetaminophen). The indication has not been expanded. Thus, approved use of Euflexxa is quite narrow.
- 92. Euflexxa is a physician-administered product, which means that it can only be administered in a physician's office.
- 93. Euflexxa has been a very profitable product for Ferring, averaging some \$100 million in annual sales. Even so, Euflexxa is a commodity product, as there are many comparable products on the market and none is more effective (or better tolerated) than any other. This has increased pressure on Ferring sales representatives to use improper inducements to differentiate Euflexxa from the competition, especially given that Euflexxa is more expensive and no more efficacious than its competitors' products and because the reimbursement process for Euflexxa is often more costly and burdensome for physicians' offices than the alternatives.
- 94. As discussed more fully below, Ferring has met these challenges, and improperly expanded the market for Euflexxa, by offering physicians a series of improper financial inducements to prescribe Euflexxa as well as promoting the device using unsubstantiated superiority claims, which rendered it misbranded. In the process, both patients and Government Programs have been defrauded.

### VII. FERRING'S RETALIATION AGAINST RELATOR

- 95. Ferring illegally terminated Relator in direct retaliation for his having come forward to report the Company's marketing of Euflexxa, including its illegal sampling activities, kickbacks, best price scheme and illegal "superiority" promotion.
- 96. Beginning in early January 2011, Relator was encouraged by his District Manager, Susan Schwartz, to sell Euflexxa by: (i) providing large quantities of free samples to induce physicians to prescribe greater quantities of Euflexxa; (ii) "marketing the spread" between what physicians would pay for the product and what they ultimately would be reimbursed for by Medicare; and (iii) promoting the "superiority" of the product despite the utter lack of clinical evidence supporting such a claim. In addition, Ms. Schwartz gave Relator, for use in his job, copies of detail pieces and promotional literature to assist him in this illegal promotional conduct. Ms. Schwartz's directives constituted violations of Ferring's own compliance code, as well as multiple federal and state laws.
- 97. Relator was immediately uncomfortable with these illicit directives, and informed Ms. Schwartz that he would not follow them. Instead, Relator focused on making sales within the confines of FDA regulations governing promotional activities. Relator was successful, securing high sales numbers from the start and earning praise for his efforts. Specifically, on January 11, 2011, Ms. Schwartz congratulated Relator, in an email sent to him and other sales representatives in his district, for leading the district in weekly sales of Euflexxa by a significant margin.
- 98. Despite his early success, Relator remained troubled by the conduct of his District Manager and her insistence that he employ the illegal practices outlined above. Having previously expressed to Ms. Schwartz his discomfort with her directives, and having received no

relief from her, on February 10, 2011, Relator reported the illegal promotional activities that Ms. Schwartz had encouraged him to carry out to Ferring's Chief Compliance Officer, Jean Frydman. In addition, Relator faxed to Ms. Frydman the documents given to him by Ms. Schwartz regarding "marketing the spread" as well as the materials he was provided that touted the "superiority" of Euflexxa.

- 99. On February 14, 2011, Relator and Ms. Frydman spoke by telephone, during which Relator, in more detail, informed Ms. Frydman about the illegal kickback and "superiority" promotional tactics and related literature that Ms. Schwartz had encouraged him to use.
- 100. In reporting to Ms. Frydman these fraudulent and illegal marketing schemes and practices, Relator specifically and in substance informed Mr. Frydman of his belief that Ferring was in violation of federal and state healthcare laws and regulations, and thus put Ferring on notice that it could be liable under the federal and state False Claims Acts.
- 101. On February 17, 2011, Ms. Frydman informed Relator that Ferring was conducting a compliance investigation in connection with his allegations, and that he should not attend an upcoming national sales meeting in Orlando, Florida while the investigation was underway. Later, Ms. Frydman instructed Relator in an email that, if asked by his district colleagues why he was not attending the national sales meeting, he should state that something urgent and unexpected had come up, and that he could not attend.
- 102. Meanwhile, on February 15, 2011, in an email sent to Relator and his district colleagues, Ms. Schwartz again congratulated him for leading the district in weekly sales of Euflexxa by a significant margin.

On March 2, 2011, Ms. Frydman interviewed Ms. Schwartz regarding Relator's allegations. On March 8, 2011, Ms. Frydman conducted a telephone call with Relator during which she informed him of the results of Ferring's investigation into his allegations, and actually read Relator the findings from the investigation report verbatim. In the report, which she told Relator was four pages long, Ms. Frydman confirmed his allegations were correct and substantiated, and that Ms. Schwartz had violated company policies and federal law, including, potentially, the False Claims Act. Ms. Frydman further informed him that, as a result of Ms. Schwartz's actions, Ferring was terminating her employment, effective March 8, 2011. Importantly, Ms. Frydman informed Relator during the call that Ms. Schwartz had confirmed to Ms. Frydman that these illegal promotional practices were commonplace within the Company across every district in the country.

On March 9, 2011, Ferring conducted a nationwide conference call for its entire sales force. On the call were the following Ferring management employees: Jay Sachnoff, Ferring's National Sales Director; Alisha Haines, Ferring's Regional Sales Director; Ms. Frydman; Karen DiSanto, Ferring's Director of Human Resources; and Paul Froisland, Ferring's Human Resource Manager. During that call, Ferring management instructed the sales representatives who worked in orthopedic sales across the country to send all of their promotional literature to Ferring's headquarters in New Jersey in order to allow Ferring to ensure its propriety. During the call, Mr. Froisland stated that Ferring was taking this measure due to a complaint from a newly-hired sales representative—a transparent reference to Relator, the only "newly-hired" sales representative on the call—about illegal promotional violations, in direct retaliation for his reporting activities.

- On March 14, 2011, Alisha Haines, Ferring's Eastern Regional Sales Director, informed Relator via telephone that Relator would be coming to Ferring's headquarters in New Jersey for IPAD training. This particular training had been previously provided at the national sales meeting in Orlando, which Relator had been directed not to attend. Ms. Haines instructed Relator to make travel arrangements such that he would arrive at headquarters by 7:00 a.m. the following morning. Later that same day, Ms. Haines called Relator to inquire as to whether he had made flight arrangements to New Jersey. Relator responded that he had not as he had been in the field working all day and explained that he was on his way home to make the reservations and pack his bags. Ms. Haines replied that Relator should hold off making flight arrangements until she called him back. A couple of hours later, Ms. Haines called to tell Relator that he should not bother making flight arrangements to New Jersey, and that she would be in touch the following morning with instructions for "next steps."
- 106. The next morning, March 15, 2011, Ferring terminated Relator's employment. Ferring ambiguously informed Relator that his termination was based on insubordination by failing to file paperwork in connection with a management directive (i.e., making the travel arrangements to New Jersey).
- 107. Ferring's written compliance rules encourage employees to express any concerns that they may have about certain Ferring practices without fear of retaliation. According to the "The Guide: Summary of Ferring Policies on Business Conduct," employees are instructed to "[s]peak out when [they] think wrongs are being committed in Ferring's name." In addition, The Guide provides: "If you think someone may be violating a law or policy, please take steps to address the situation by speaking with the person directly or by notifying your supervisor, Human Resources or the Legal Department."

- Relator relied upon Ferring's reporting policy and provided Jean Frydman, Ferring's Chief Compliance Officer, with specific information regarding sampling directives and activities that he believed, in good faith, were in violation of Ferring's policies and Federal law (including the False Claims Act) insofar as the Company: (i) provided something to a customer in exchange for any implicit or explicit agreement or understanding to use, purchase, order, recommend, prescribe or dispense any Ferring product; (ii) improperly used prescription product samples other than in response to a licensed practitioner's written request; and (iii) improperly promoted the "superiority" of Euflexxa in an effort to maximize sales.
- 109. In response to his complaints, beginning in February 2011, Ferring began systematically to retaliate against Relator for his whistleblowing activity, creating a hostile work environment. First, he was forced to miss an important national sales meeting in Orlando, Florida that was attended by all of the Company's sales representatives. Shortly thereafter, Relator was singled out during a nationwide conference call for having complained about illegal promotional practices. Then, less than a week later, Ferring wrongfully terminated Relator in retaliation for his whistleblowing activities.
- Relator a merit increase at the beginning of March 2011. This merit increase was given to every Ferring sales representative in Relator's region other than him, despite the irrefutable fact that Relator's sales figures were consistently at or near the top of all the sales performances in his region from the time he was hired until he was wrongfully terminated. In fact, Susan Schwartz confirmed to Relator in early 2011 that he had earned a two to four percent raise as a result of his sales performance. However, in a subsequent letter from Karen DiSanto, Ferring's Senior Director of Human Resources, dated March 9, 2011—not coincidentally less than one month

after Relator reported the illegal conduct to Ferring—Ms. DiSanto revealed that Relator would not be receiving a merit increase.

- 111. Ferring also denied Relator the commission that he had rightfully earned based on his sales of Euflexxa. According to Ferring's bonus structure for the first quarter of 2011, a sales representative promoting Euflexxa was entitled to \$3 per box for attaining 70-99% of their quarterly sales goal. A \$5 per box bonus was awarded for those representatives who achieved 100% of their quota. An additional \$13 per box "kicker" was awarded for every unit sold above the quarterly goal. For the first quarter of 2011, Relator exceeded his sales goal of 581 boxes, entitling him to a substantial commission under the Company's bonus structure. Instead, as further retaliation against Relator for his whistleblowing activities, the Company never paid Relator the commission that he had, in fact, earned.
- 112. Ferring plainly took adverse employment action against Relator in the form of his termination as a direct response to his internal reporting. Until he was terminated, Ferring never informed Relator that he had any performance issues. To the contrary, as noted above, Ferring highly valued Relator based on his superior performance among his peers, and expressed this sentiment to him on more than one occasion.
- 113. Ferring explicitly recognized the veracity of Relator's allegations through its investigation, by terminating Ms. Schwartz as a result of Relator's actions, and by recalling nationwide all of the sales literature used by its orthopedic sales representatives. In light of his superior work record and the absence of any performance issues, the vague reason given for his termination—*i.e.*, insubordination in not filing paperwork relating to a management directive—obviously constitutes a pretext for the termination of Relator in retaliation for his

whistleblowing. Lastly, it was only within a relatively short period of time after Relator reported the marketing violations to Ferring's compliance officer that the Company terminated him.

- 114. Following his termination, Relator sought to recover from Ferring the bonus and merit increase he had been promised. Ferring responded with an entirely new set of fictitious reasons for why he had been terminated. These fabricated justifications included allegations that he had cancelled field training rides, failed to pick up a company car, failed to submit weekly select expense reports, falsified company records, failed to meet sales targets, and failed to spend marketing funds allotted to him by the Company. Not only were these new purported grounds for termination completely inaccurate, none had ever been presented to Relator as grounds for discipline, much less as a basis for his termination. Rather, Ferring's response was simply more of the same—trumped up, pretextual reasons that were manufactured by the Company in an attempt to cover up its illegal retaliation against Relator
- 115. As a direct and proximate result of this unlawful and repeated harassment and retaliation, Relator has suffered emotional pain and mental anguish, together with serious economic hardship.

#### VIII. THE FRAUDULENT KICKBACK SCHEME

116. The plan and purpose of the Fraudulent Kickback Scheme was to (i) provide free "samples" of Euflexxa to physicians for their commitment to purchase additional quantities of Euflexxa at commercial rates; (ii) encourage physicians, many of whom did, to seek reimbursement from Federal Programs for the use of the free samples; (iii) induce physicians to prescribe Euflexxa by marketing the "spread" between what they would pay to purchase the device, and what they would be reimbursed by Government and private insurers to prescribe it; (iv) use speaker programs and other financial incentives to encourage and reward "key opinion"

leaders" who agreed to promote and prescribe Euflexxa; and (v) directly assist and facilitate the reimbursement of claims for Euflexxa through "free" reimbursement assistance programs (collectively, the "Fraudulent Kickback Scheme").

- These actions violated both the Federal AKS, 42 U.S.C. § 1320a-7b(b), and the PDMA, 21 U.S.C. §§ 353, *et seq.*, because they were taken to induce customers to buy and prescribe Euflexxa.
- 118. The Fraudulent Kickback Scheme has been a financial success for Ferring because it was intended to, and did, result in the purchase and dispensing of Euflexxa, and subsequent reimbursement of those purchases by Government Programs. The physicians also profited from this arrangement.

## A. FERRING PROVIDES FREE SAMPLES AS KICKBACKS TO INDUCE COMMITMENTS TO PRESCRIBE EUFLEXXA

- Since its approval by the FDA in 2004, Euflexxa has been an expensive device with a lone approved use. Compounding the challenge of making the medical device profitable, it competed against a wide range of similar HA products, including Orthovisc® (Depuy), Synvisc® (Genzyme), Hyalgan® (sanofi-aventis), Supartz® (Smith & Nephew), and an array of generic products. Because each of these HA products treats the same condition using the same general scientific method, Ferring found itself having to promote and sell Euflexxa in a commodity market in which it was increasingly difficult to differentiate its product from other competing HA products, such that marketing schemes and gimmicks have tended to drive market share. Ferring recognized that sampling could be very effective in gaining market share from its competitors' products.
- 120. However, companies such as Ferring may not provide samples to health care professionals:

- (i) if the health care professional intends to seek reimbursement from the Government for the sample;
- (ii) if the health care professional intends to use the sample for his or her own personal use; or
- (iii) to reward the health care professional for his or her past prescribing habits, or as a financial inducement to encourage future prescriptions.
- Nevertheless, Ferring routinely, systematically, and intentionally has engaged in a nationwide, fraudulent kickback scheme by which it provides physicians with free samples of Euflexxa in exchange for commitments by those doctors to purchase and prescribe Euflexxa, which these physicians would then bill to payors, including Medicare, Medicaid, and other Government Programs. In this manner, Ferring sought to, and did, improperly influence prescribing and utilization decisions for Medicare, Medicaid and other Government Program beneficiaries throughout the United States.
- Since at least as early as 2010 (and considerably earlier, each free sample of Euflexxa was generally worth approximately \$150, depending on the applicable reimbursement rate under Federal health care programs. During this same time period, Ferring instructed and required that members of its sales force, including Relator, distribute free samples of Euflexxa as bribes to a wide array of health care professionals.
- 123. The sales force was not given any guidance or restriction on the number of samples that they were permitted to distribute or the physicians who could receive them, although sales representatives were provided up to 450 samples per month. Sales representatives were only instructed to distribute as many Euflexxa samples as was necessary to increase sales and meet their generally unrealistic sales quotas. Thus, the distribution of samples was guided

only by the sales representatives' knowledge that if they did not grow sales volume to meet corporate expectations, they would be fired.

- When ordering samples, the sales representatives entered into a Ferring database the number of samples requested and the identity of the physician who received the samples. To ensure control and delivery of the free product, Ferring distributed the Euflexxa samples directly to the physicians from the Company's own distribution facility. Included within each delivery was a corresponding sample form that the physician was required to sign. Then, every month, the Company distributed reports to the sales force that included information about who was getting free samples and in what quantities. The clear message was that, given the intensely competitive nature of the HA market, samples drove sales. At no time during his employment did Relator get any push back from Ferring on the number of free samples he was ordering for his customers upon their request—despite the fact that, at times, Relator was, at Susan Schwartz's direction, handing out approximately one hundred free syringes a month.
- Notwithstanding the relatively small patient population for Euflexxa, Ferring issued nearly 250 sample syringes (worth some \$37,500) between December 6, 2010 and March 2011—an average of approximately 80 samples per month—despite the fact that Relator was only selling approximately 200 syringes per month during that same time period. Annualized, this meant that a sales representative like Relator received some \$360,000 in free samples each year to induce prescribing of Euflexxa.
- 126. Each Euflexxa sample kit, which contains three syringes, was, in and of itself, an entire course of therapy for a patient. Thus, these samples were not designed for physicians or patients to "test" before committing to Euflexxa therapy; rather, they were plainly intended at all

times material hereto as inducements to prescribe additional quantities of Euflexxa in lieu of alternative HA products.

- 127. Ferring, through its local managers, instructed Relator and others to use the samples to induce physicians to prescribe Euflexxa in lieu of competitors' HA products (or no HA products at all), or to reward physicians who already prescribed Euflexxa in large quantities. Thus, high prescribers of Euflexxa tended to receive more samples than other physicians.
- 128. For example, Ferring provided Dr. Randall Peyton, an orthopedic surgeon located in Sterling, Virginia, with considerable quantities of free syringe samples of Euflexxa in exchange for his continued use of the medical device as well as his agreement to use his influence over other community physicians who treated osteoarthritis of the knee. In fact, the sales representative who operated in Relator's territory prior to December 2010, Somu Awatramani, had consistently plied Dr. Peyton (recognized as one of the country's highest prescribers of Euflexxa) with hundreds of free samples of Euflexxa. This leveraging of free samples paid off, leading Dr. Peyton to purchase a single order of 1,500 syringes—the largest one-time purchase of Euflexxa in the Company's history.
- Even after Awatramani had been promoted to a Ferring Sales Operations position in the fall of 2010, he continued personally to carry out Ferring's sampling scheme, giving Dr. Peyton an average of 100 free samples (worth \$150 each or a total of \$15,000) per month, or what would amount to some \$180,000 in "free" samples per year. In return, Dr. Peyton ordered between 400 and 500 syringes of Euflexxa on a monthly basis. In other words, in exchange for Dr. Peyton's continued loyalty to Ferring, the Company ensured that he received approximately 20% of the Euflexxa he prescribed for free.

- 130. To repay him for his loyalty to Euflexxa, Ferring also paid Dr. Peyton to promote Euflexxa to other physicians. Between December 2010 and early 2011, Dr. Peyton gave numerous presentations at various events, including community centers, which were attended by patients and physicians alike. During these presentations, Dr. Peyton touted Euflexxa to other orthopedic surgeons as the *only* hyaluronic acid product he used for treating osteoarthritis of the knee. Ferring paid Dr. Peyton more than \$1,000 per presentation.
- 131. Thus, for key physicians like Dr. Peyton, Ferring used samples as illegal kickbacks to reward their loyalty.
- 132. Perhaps more alarming, because the samples were enough for a full course of therapy, many physicians would, albeit illegally, use the samples to treat patients and then submit claims for reimbursement of the samples' retail price to the patients' insurance payor—which, given the patient population for Euflexxa—frequently was a Government Program.
- 133. Ferring's use of free samples as inducements to leverage sales was against Ferring's own policies, which required that "[n]o Ferring employee may provide anything of value to a healthcare provider for the purpose of inducing the provision of services or the sale or prescribing of [its] products."

### B. FERRING SUCCESSFULLY PERSUADED HEALTH CARE PROVIDERS TO SEEK REIMBURSEMENT FROM FEDERAL PROGRAMS FOR USE OF THE FREE SAMPLES

134. In furtherance of its fraud, Ferring management instructed its sales representatives to encourage health care professionals, including front office staff, to seek reimbursement for the free samples the Company provided. And, in many instances, health care professionals actually sought reimbursement for these free samples from Federal Programs, including Medicare and Medicaid.

- Somu Awatramani, his predecessor in the region sales area, had been long responsible for not only providing large quantities of free samples of Euflexxa to customers (such as Dr. Peyton), but also subsequently encouraging these health care providers to actively seek reimbursement for the free product provided, which they often did. Relator learned this directly both from Awatramani himself and from customers who indicated that this had been Ferring's practice prior to Relator's assuming of the sales region.
- 136. For example, Dr. Randall Peyton, one of Ferring's premier Euflexxa prescribers, submitted claims to Medicare for over 900 Euflexxa services in 2012 alone, at an average claim of \$240 per service, and for which Dr. Peyton ultimately sought \$219,120.00 in reimbursement from Medicare. *See* Exhibit A. Each of those claims constituted a false claim as the direct result of Ferring's fraudulent marketing scheme. Ferring knowingly caused these false claims to be submitted in violation of the federal False Claims Act.
- Northern Virginia Osteo and Rheumatology in Manassas, Virginia, with free samples and speaking engagements. During 2012, Dr. Ghafouri billed Medicare for more than 120 Euflexxa services, claiming an average \$350 per service, and for which Dr. Ghafouri ultimately sought \$42,350.00 in reimbursement from Medicare. *See* Exhibit A. Each of those claims constituted a false claim as the direct result of Ferring's fraudulent marketing scheme. Ferring knowingly caused these false claims to be submitted in violation of the federal False Claims Act.
- 138. Ferring also targeted Dr. Bruce Edwards, an orthopedic surgeon practicing in Hagerstown, Maryland, with free samples and speaking engagements. During 2012, Dr. Edwards billed Medicare for nearly 250 Euflexxa services, claiming an average \$195 per service,

and for which Dr. Edwards ultimately sought \$48,160.00 in reimbursement from Medicare. *See* Exhibit A. Each of those claims constituted a false claim as the direct result of Ferring's fraudulent marketing scheme. Ferring knowingly caused these false claims to be submitted in violation of the federal False Claims Act.

- 139. Exhibit A contains additional examples of physicians who Ferring targeted with its fraudulent marketing scheme. The exhibit specifies the precise number of claims submitted to Medicare that were rendered false as the direct result of Ferring's fraudulent scheme. The exhibit also details the amounts sought by the physicians and the monies actually paid by Medicare for these false claims.
- 140. Similarly, Relator regularly called upon OrthoBethesda, an orthopedics group located in Bethesda, Maryland, which typically ordered 150 boxes (350 syringes) of Euflexxa every six to ten weeks. On one particular visit, Relator spoke with the office manager about ordering more Euflexxa. After agreeing to purchase 25 boxes (75 syringes) during this visit, the office manager stated that the group wanted an equal amount in free samples so that they could bill for them—a clear reflection of the illegal business arrangement previously established by Ferring and Awatramani.
- That the free samples were simply part of the stock of Euflexxa that physicians could use and bill the Government and other payors was clear from the fact that they were commingled with the Euflexxa stock which had been purchased. Relator learned directly from calling on the doctors who were regular recipients of Ferring's largesse, that Ferring's physician customers, including Dr. Randall Peyton, generally did not store the free samples received from the Company separately from the product actually purchased from Ferring. Moreover, because the sample syringes had no distinct markings on them designating them as being free products or

samples, once a health care professional pulled a Euflexxa syringe off the shelf and administered the treatment to a patient, there would be no practical means of knowing whether any subsequent billing for that treatment was for a free sample or a purchased product. Ferring knew that by inundating physicians with large quantities of free samples, physicians would ultimately seek reimbursement for Euflexxa samples, even from Government programs like Medicare and Medicaid.

- 142. Ferring knew that its samples kickback scheme was illegal. In its own guidance documents, Ferring explains the Anti-Kickback Act and the type of conduct the law is designed to prevent. Specifically, Ferring acknowledges that services used as "unlawful inducement[s] to purchase a product [] triggers the anti-kickback statutes and the False Claims Act." *See* Ethical Promotion of Pharmaceutical Products, Policy Series 100, *available at* http://www.ferringusa.com/files/mktg\_sales\_policy\_v2.pdf (last visited January 20, 2012).
- But Ferring provided abundant free samples of Euflexxa to physicians precisely to increase sales of Euflexxa and, thus, Government Program reimbursements in violation of both the AKS, 42 U.S.C. § 1320a-7b(b), and the PDMA, 21 U.S.C. §§ 353, *et seq*.
- 144. The Ferring managers and employees involved in the Fraudulent Kickback Scheme knew that it was illegal to provide free Euflexxa samples in exchange for physician agreements to purchase additional quantities and/or to influence other physicians to prescribe Euflexxa.
- 145. For example, Susan Schwartz, Relator's District Manager, would, as a matter of course, review with each sales representative the top targets on the account lists. Ms. Schwartz instructed Relator that each of the top targets were to be rewarded for their prescribing with free samples of Euflexxa. Ms. Schwartz explained that the distribution of free samples benefited

Ferring in two critical ways. First, the free samples helped ensure that Ferring maintained the continued business of a high prescribing physician. Second, for accounts or physicians who were not yet using Euflexxa (or not prescribing the device in quantities deemed sufficient by Ferring), the free samples served as a financial inducement to encourage increased use of the Company's product instead of a competitors' product or no HA product at all.

### C. FERRING INDUCES PHYSICIANS TO PRESCRIBE EUFLEXXA BY "MARKETING THE SPREAD"

A significant component of Ferring's Fraudulent Kickback Scheme was the manner in which it encouraged physicians to prescribe Euflexxa in lieu of alternative therapies by telling the physicians that they personally would earn a greater profit on Euflexxa than on its alternatives. Specifically, Ferring instructed its sales representatives, including Relator, that they should demonstrate to physicians that the "spread" between the price they would pay to purchase Euflexxa and the amount they would be reimbursed by Government Programs and other insurers for prescribing it would be greater than the "spread" available to them for buying and prescribing alternative therapies. Ferring called this "marketing the spread," and it was highly effective.

147. "Marketing the spread" is an industry term which describes a manufacturer's practice of inflating the prices used by Medicare and other federal programs as the basis for reimbursement of the device, while deeply discounting the price paid by physicians (or giving the device to physicians for free). The spread is marketed to physicians as a way of increasing their profits when they receive reimbursement for the device from Medicare and other health programs. This manipulation of the pricing enables pharmaceutical companies to offer doctors kickbacks—i.e., the spread is marketed to doctors as a reason to prescribe that product in preference to a therapeutic equivalent.

- 148. In order to assist them in "marketing the spread," Ferring provided its sales representatives with copies of available pricing contracts for healthcare providers in their sales territories. These contracts typically involved purchase volume commitments and associated pricing discounts. Sales representatives were then instructed to promote those contracts to their sales targets by highlighting areas in which the profit margin available to the healthcare provider was greater with Euflexxa than it would be if the healthcare provider bought and prescribed a competitor product.
- 149. For example, Susan Schwartz, Relator's District Manager, provided Relator with an excel spreadsheet that set forth a "Cost Analysis For Patients with MEDICARE." Ms. Schwartz instructed Relator to use the cost analysis as a promotional tool when detailing physicians and their office staff. The spreadsheet sets forth how much profit a physician stood to gain based on the volume of Euflexxa purchased.
- 150. For example, if a physician were to purchase one to nine boxes, the cost per box was \$399.95, or \$133.32 per syringe. With Medicare reimbursing the physician at \$148.53 per syringe, the spreadsheet shows the profit per syringe at \$15.21 and \$45.64 per box, for a "marginal difference" of 11%. However, if the physician were to purchase 300 or more boxes, the cost per box drops significantly to \$320 per box, or \$106.67 per syringe. Factoring in the Medicare reimbursement at \$148.53 per syringe, Ferring's spreadsheet informs the physician that he or she stood to profit \$41.86 per syringe and \$125.59 per box, for a "marginal difference" of 39%. In other words, according to Ferring's "cost analysis", a physician could generate nearly \$38,000 in extra income by purchasing 300 boxes of Euflexxa.
- 151. The spreadsheet also lists the Medicare payment limits for Euflexxa's competitors in an effort to highlight the pricing opportunity from purchasing Euflexxa over the other products

in its class. Because Ferring was able to manipulate the price of Euflexxa to create a significant margin when compared to the established Medicare reimbursement rate, it could induce physicians to purchase more of the product at a profit.

152. Plainly, Ferring was promoting Euflexxa over competitor products based not on its efficacy or suitability for a particular patient population, but rather on a "pricing opportunity" that would permit the healthcare provider to pocket an additional \$38,000 by prescribing Euflexxa instead of a competing device. Coupled with the other inducements the Company was providing, promoting the profit physicians could make was an illegal inducement to purchase Euflexxa, which would in turn cause false and/or fraudulent claims to be submitted to the Government.

### D. FERRING INDUCES PHYSICIANS TO PRESCRIBE EUFLEXXA BY REWARDING THEM WITH LUCRATIVE SPEAKING ENGAGEMENTS

- 153. Ferring has adopted a sales model that incentivizes physicians to prescribe Euflexxa by rewarding them with lucrative speaking engagements as a quid pro quo. Relator was directed by his District Manager, Susan Schwartz, to identify and procure speakers who were high prescribers of the product.
- 154. Physicians were active and enthusiastic participants in this corrupt practice. For example, as discussed, Dr. Randall Peyton of Sterling, Virginia, is one of the highest-volume prescribers of Euflexxa in the entire country. In return for Dr. Peyton's continued loyalty, Ferring paid him to conduct multiple speaking engagements. Not coincidentally, Dr. Peyton earns considerable money from Ferring for being one of the most prominent national speakers for the product.
- 155. Conversely, Ferring punished those physicians who were not, in Ferring's estimation, prescribing enough Euflexxa, by refusing to retain those physicians for lucrative

speaking engagements. For instance, Relator went to Ms. Schwartz and Ferring's Marketing Department to get approval for Dr. Mohsen Ghafouri, a rheumatologist in Manassas, Virginia, to be a speaker on behalf of the Company. Despite Dr. Ghafouri's interest in conducting speaker programs, Ferring's Marketing Department denied Relator's request, explaining that Dr. Ghafouri was not writing enough prescriptions of Euflexxa and was, in Ferring's view, prescribing too much Hyalgan®, a competing product.

156. By conditioning a physician's inclusion as a member of the Company's lucrative speaker bureau on their prescribing habits, Ferring's speaker program was, in substance and intended effect, an illegal *quid pro quo*, and hence the payments that Ferring made to cooperative prescribers for using Euflexxa constituted unlawful remuneration knowingly intended to induce or reward purchases of Euflexxa — conduct that runs afoul of the Anti-Kickback Act, and hence causes the submissions of false claims in violation of the federal and state False Claims Acts.

# E. FERRING PROVIDES ADDITIONAL INDUCEMENTS, INCLUDING CONTRIBUTIONS TO CUSTOMERS' FAVORED CHARITIES AND FREE LUNCHES TO INDUCE PHYSICIANS TO PRESCRIBE EUFLEXXA

- 157. Ferring provides other inducements to persuade physicians to prescribe Euflexxa, including making contributions to physicians' favored charities and buying customers free lunches in exchange for agreements to make future purchases of the product.
- 158. During his initial meeting with Susan Schwartz and Somu Awatramani at a Washington, D.C. restaurant soon after being hired, Awatramani explained the tactics he had used with Euflexxa customers in Relator's new region. Included among these tactics were insights as to what inducements were effective in securing certain customers' promises to purchase Euflexxa.

- 159. For example, Awatramani explained to Relator that Loudoun Spine & Rehabilitation in Leesburg, Virginia would simply purchase Euflexxa in exchange for his provision of free meals for the office. Specifically, Awatramani advised Relator that "[t]he more you feed them, the more they order" Euflexxa. According to Awatramani, free lunches were an integral part of Ferring's promotion of Euflexxa.
- In addition, Awatramani revealed that Ferring used charitable contributions as a means to induce physicians to prescribe Euflexxa. He informed Relator that Ferring sponsored the Prince George's County Arthritis Walk held on May 1, 2010, in exchange for the agreement by Arthritis and Pain Associates of Prince George's County in Greenbelt, Maryland to purchase future quantities of Euflexxa. Ferring leveraged these donations to favored charities to induce physicians to prescribe its medical device. Such practices clearly violate the Anti-Kickback Statute and the Office of the Inspector General for the Department of Health and Human Services' ("OIG-HHS") guidance, which describes "contributions determined in any manner that takes into account past or expected prescriptions, orders, or purchases of items or services payable by any Federal health care program" as a violation. *See* U.S. Department of Health and Human Services, Office of Inspector General Advisory Opinion No. 08-02 (issued Jan. 29, 2008).

# F. FERRING OFFERS ILLEGAL REMUNERATION IN THE FORM OF FREE REIMBURSEMENT AND REFERRAL SERVICES TO INDUCE PHYSICIANS TO PRESCRIBE EUFLEXXA

- 161. Ferring has developed and manipulated its own Medicare and Medicaid reimbursement support services for the express purpose of increasing sales of Euflexxa.
- 162. One tool in each Ferring sales representative's bag was Ferring's commitment to assist physicians in maximizing their reimbursement dollars. Indeed, Ferring went out of its way

to help physicians obtain generous reimbursements for prescribing Euflexxa, going so far as to offer Euflexxa reimbursement support, which developed as a free service to help physicians receive optimal reimbursement.

- 163. Tellingly, in the Euflexxa Training Manual, an entire module is dedicated to educating sales representatives about the intricacies of the billing and reimbursement processes and strongly emphasizes its importance in the promotion and success of Euflexxa. The training materials explicitly state that "[c]oding, coverage, and reimbursement . . . must be understood in order to effectively market Euflexxa and facilitate its adoption by physicians and patients." The materials further indicate that "[d]ue to the fact that the occurrence of osteoarthritis increases significantly with age, it follows that Medicare is the key payer for treatments, followed by private sources, other funds, and Medicaid." Later in the training materials, Ferring provides reimbursement guidance on the coverage, coding and reimbursement of Euflexxa, as well as competing products (e.g., Supartz® and Hyalgan®), specifically as it relates to Medicare and Medicaid. Plainly, Ferring understood that maximizing reimbursement dollars was a key incentive for physicians to prescribe Euflexxa.
- In addition, Ferring also operated, and continues to operate, a "Reimbursement Hotline" to assist physicians with coverage, coding and reimbursement of Euflexxa, as well as assisting in reversals of denials of coverage. Notably, the Euflexxa Reimbursement Hotline website explicitly outlines four key areas in which Ferring may provide assistance to medical professionals and billing staff. These areas include: (i) insurance verification for specific patients; (ii) suggested coding for Euflexxa therapy; (iii) obtaining prior authorization; and (iv) appealing denied or unpaid claims.

And, the Euflexxa Reimbursement Hotline website provides important guidance to physicians regarding how their claims for reimbursement should be worded if they are to be paid. For example, the Euflexxa Reimbursement Hotline website notes that when filing claims for Euflexxa, physicians must indicate an ICD-9-CM diagnosis code indicating the patient's condition, including:

**715.16** – Osteoarthritis, localized, primary, lower leg

715.26 – Osteoarthritis, localized, secondary, lower leg

**715.36** – Osteoarthritis, localized, primary/secondary unknown, lower leg

715.96 – Osteoarthritis, generalized/localized unknown, lower leg

166. Ferring's reimbursement training materials direct its sales representatives to encourage physicians and their office staff to consult the free Euflexxa Reimbursement Hotline to assist in any "reimbursement or billing complication." Reinforcing the importance of the free reimbursement services the Company provides, Ferring makes clear to its sales representatives that "[a] strong correlation exists between a representative's success in promoting Hotline service utilization and overall sales impact." In other words, in the event that a doctor's office wanted assistance with the appeal of a Euflexxa claim denial, Ferring offered a "free" service to assist those physicians' offices.

167. The "free" reimbursement service became a key part of sales representatives' detail to physicians to overcome objections for prescribing Euflexxa, and it remains a key resource for sales representatives in the promotion of Euflexxa. Without assistance, reimbursement issues may be costly to physicians in two ways. First, in the event of a denied claim for coverage, a medical practice must bill the patient for devices already provided. Given the high cost of many of these drugs and devices, patients may be unable to afford payment. If

this cost is beyond the patient's means, the practice may then be required to assume the cost of the "buy and bill" device itself.

168. Even in the event that coverage is eventually approved, the process of obtaining that coverage can be costly for physicians and their staffs, requiring time-consuming interaction with payors. Prior authorizations are a payor management tool that most affects therapy utilization. Prior authorizations may be costly for patients as well, requiring them to postpone treatment until a coverage decision is reached. For all of these reasons, reimbursement concerns have been a frequent physician objection against prescribing Euflexxa.

Such objections were particularly prevalent with regard to products like Euflexxa, which are more expensive and no more efficacious than competing products. When prescribing less expensive, competing products, coverage denials are relatively unlikely, and the reimbursement process is simple and straightforward. However, when prescribing a more expensive, but equally effective product, coverage denials are increasingly likely, and the reimbursement process becomes correspondingly more time-consuming and complicated. A physician who writes a prescription for a more expensive product, and in turn a member of that physician's staff who processes the paperwork, may be required to spend considerable time interacting with the patient's insurance payor or a Government Program, arguing that the particular circumstances of the patient justify coverage of the prescription. The difficulty of arguing the physician's case increases when the alternative therapy is significantly more expensive, as has been the case with Euflexxa. All else being equal, physicians are inclined to prescribe the cheaper regimen rather than the more expensive product in order to simplify the reimbursement process.

- 170. The Office of the Inspector General for the Department of Health and Human Services ("OIG-HHS") has offered its insight on the subject of reimbursement support services, suggesting that such services are highly susceptible to fraud and abuse in Federal Programs, including Medicare and Medicaid.
- 171. For example, in an advisory opinion issued on October 3, 2006, the OIG responded to an inquiry regarding the propriety of a seller of durable medical equipment ("DME") offering free reimbursement consulting services to some of its customers. *See* OIG-HHS, Adv. Op. No. 06-16 (issued Oct. 3, 2006). The referenced "reimbursement consulting services" included: (i) general claims submission information, such as advice on how to code products; (ii) reviewing claims; (iii) helping to appeal denied claims; and (iv) providing assistance related to medical justification for receiving particular products. *Id.* at 2. The OIG found that these reimbursement services constituted remuneration and that because the DME suppliers were "in a position to generate Federal health care program business" for the customers, offering such services "clearly" implicated the Federal AKS, 42 U.S.C. § 1320a-7b(b). *Id.* at 4.
- "would be neither limited in nature, nor free-standing," noting that the free services "would potentially confer substantial independent value upon the DME supplier." *Id.* at 5. The OIG also stated that any assistance "securing Federal reimbursement for individual beneficiaries to receive particular products could cause beneficiaries to receive greater quantities of, or more expensive" product than they actually require. *Id.* In addition, such reimbursement services would tend to provide a financial incentive to steer customers to purchase the supplier's products, "even if products from other manufacturers were less expensive or more appropriate."

In this instance, Ferring's offer of free reimbursement support services causes physicians to prescribe (and patients to receive) the more expensive treatment in the form of Euflexxa. Also, as the OIG notes, Ferring's free Reimbursement Programs are being used as financial incentives to persuade physicians to use Euflexxa despite the fact other products from different manufacturers are equally effective and cheaper. Much like the DME scenario outlined in the advisory opinion, the Euflexxa Reimbursement Programs, as the OIG concludes, were simply a "vehicle to pay unlawful kickbacks" to Ferring's customers in an effort to increase sales.

In a second advisory opinion, the OIG determined that any services, including pre-authorization services, that save a physician's office staff time, result in a realization of savings, or which were designed to refer or induce the purchase of a manufacturer's products could constitute unlawful remuneration and thus implicate the anti-kickback statute. *See* OIG-HHS, Ad. Op. No. 10-04 (issued Apr. 30, 2010). The Euflexxa Reimbursement Programs are specifically designed to influence prescribing and utilization decisions by making it easier and less burdensome for a physician to prescribe Euflexxa and ultimately obtain reimbursement from Federal Programs like Medicare and Medicaid.

# IX. THE FRAUDULENT MARKETING SCHEME: FERRING MAKES UNSUPPORTED "SUPERIORITY" CLAIMS TO INFLUENCE THE PRESCRIBING OF EUFLEXXA

175. Under intense competitive pressure, Ferring makes unsupported superiority claims as to Euflexxa's safety and efficacy to influence the prescribing of Euflexxa over other products in its class.

176. Specifically, Ferring utilized a sales message centered on Euflexxa having a "superior" safety and efficacy profile as compared to its competitors. Such comparisons are

prohibited by the FDA in the absence of two adequate, well-controlled studies in which the devices were compared head-to-head using comparable dosage regimens or a single, large, well-controlled study. Ferring instructed its personnel to use this scheme in order to persuade healthcare professionals to prescribe Euflexxa in lieu of the other HA products, and in violation of the applicable laws and regulations described above, including 21 C.F.R. § 202.1 et seq.

- 177. A key component of the unsubstantiated safety sales message for Euflexxa is that it has a "superior" profile with regards to (i) the fact that it is the only non-avian HA product, and thus is more "pure"; (ii) its "biorestorative" qualities most resemble naturally-occurring, endogenous HA; and (iii) its higher molecular weight equates to greater efficacy. Despite making this a key component of its promotional strategy, Ferring has no clinical evidence to support any of these claims. As a result, Ferring is prohibited from making these comparison claims, but continues to do so on a daily basis, unencumbered by the relevant regulations.
- As described more fully below, Relator has direct and independent personal knowledge of the extent to which the Fraudulent Marketing Scheme has focused on promoting Euflexxa's "superiority." Relator estimates that the majority of patients receiving Euflexxa are Government Program beneficiaries—especially Medicare beneficiaries.
- 179. Beginning at least as early as 2010, Ferring has instructed its sales force to promote Euflexxa as the "superior" choice among HA products, despite the absence of any adequate clinical studies that provide support for such claims. Importantly, properly conducted clinical trials provide the empirical data upon which the FDA determines a device's safety and efficacy and upon which doctors make professional judgments about the relative risks and benefits of a device and whether it is appropriate to prescribe for their patients.

- 180. Specifically, Ferring touts several characteristics of the device that the Company insists provide patients a clinical benefit, including that: (i) Euflexxa is the first FDA-approved HA product that is not derived from avian sources (i.e., chicken or rooster combs) and, because it is produced from "bioengineered bacteria," it is therefore more "pure" than its competitors' products; (ii) Euflexxa's "biorestorative" features most resemble naturally-occurring, endogenous HA; and (iii) Euflexxa's higher molecular weight provides an improved clinical benefit as compared to competing products of lower weights.
- None of these claims, however, is supported by any adequate, well-controlled studies in which the products were compared head-to-head using comparable dosage regimens or by any single, large, well-controlled study. Despite the lack of clinical evidence, Ferring nevertheless instructed its sales personnel to use these superiority claims to persuade healthcare professionals to prescribe Euflexxa in lieu of the other HA products, in violation of the applicable laws and regulations.
- 182. First, with regard to its status as the only non-avian HA product on the market, Ferring trains its sales force to promote "Purity In Motion"—the concept that because Euflexxa is bioengineered, it causes fewer adverse reactions. In fact, the training materials specifically state that:

The EUFLEXXA brand, therefore, must exude a 'brand personality' that reflects this advance, this superiority. In fact, we'll be differentiating EUFLEXXA from our competition by presenting our product as a bioengineered HA that offers pure relief.

The training materials include "Strategic Discussions" that highlight the takeaway message the sales representatives are to present to physicians during their sales calls. With regard to the claimed benefit of purity, Ferring instructs its sales force that "[t]he stronger your message about the unprecedented purity of EUFLEXXA, the more powerful and convincing 52

you'll be about the advantages of EUFLEXXA with respect to better tolerability." In this instance, Ferring piggybacks its unsupported superiority claims involving purity with the unproven assertion that a treatment that has greater "purity" is necessarily better tolerated as specifically compared to avian-based HA products.

- 184. Ferring also directs its sales representatives to present physicians with information about Euflexxa's avian-based competitors that aids the Company's illegal superiority claim that Euflexxa is safer than other HA products. Specifically, the Company's training materials stress that "without avian protein and residues related to chemical cross-linking, the chances of immunogenic or inflammatory reactions [e.g., pseudoseptic reactions] are dramatically reduced." Focusing on Euflexxa's "purity," sales representatives are told, "will go a long way to set up the superior tolerability and safety advantages EUFLEXXA offers."
- Second, Ferring relied heavily on the "biorestorative" quality of Euflexxa in its promotional efforts. Ferring sales representatives were repeatedly trained and instructed by the Company's marketing department to promote Euflexxa using "biorestorative" as the operable "buzz" word. In essence, Ferring claimed that Euflexxa is a superior HA product because it has a restorative effect on naturally occurring synovial fluid within the joint. This characteristic of Euflexxa, according to Ferring, enhances the viscosity, elasticity and cushioning action of healthy HA. Ferring sales representatives were directed to (and did) promote the device to physicians using this "biorestorative" sales pitch despite the lack of any clinical evidence supporting the claim generally, much less any evidence supported by a head-to-head clinical trial comparing competing HA products.
- 186. Finally, Ferring touts Euflexxa's higher molecular weight as a basis for superior performance as compared to its lower molecular weight competitors. In particular, Ferring

directed its sales force to promote Euflexxa's "superiority" on the unproven basis that higher molecular weight HA products will provide improved clinical benefit. However, Ferring never conducted any clinical studies to prove this claim of clinical benefit. Nor did the Company ever submit any clinical studies to the FDA to have this information included in its product label or to the Division of Drug Marketing, Advertising, and Communications ("DDMAC") for marketing materials.

- 187. To carry out its scheme, Ferring supplies its sales representatives with clinical literature containing the misleading superiority messaging, which the Company directed its sales force to use to promote Euflexxa. For example, in a publication sponsored by Ferring and published by Dardine & Associates (a "product messaging" consultant that services pharmaceutical companies) entitled "BioRestorative Profiling: The New View of Hyaluronic Acid Today" (the "BioRestorative Report"), the Company touts the "purification process" used in creating Euflexxa as its central "superiority" theme.
- Specifically, the BioRestorative Report was lead by Dr. Jeffrey E. Rosen—who, not coincidentally, serves as a paid consultant and a member of the Speakers Bureau for Ferring—and set out ostensibly to "review the beneficial properties of endogenous hyaluronic acid (HA), evaluate the available exogenous (i.e., derived from outside the body) HA products to determine how they compare in their resemblance to endogenous (i.e., derived internally) HA, and agree on an umbrella term that would best encompass the features of an ideal HA product for both clinicians and patients." Not surprisingly, the term selected by the Report's panel of clinicians (all of whom are also paid consultants for Ferring) was "BioRestorative"—the very same "buzz" word Ferring itself had trained its sales force on using in their promotional activities of Euflexxa. In fact, the panel notes that "BioRestorative" was selected because it

"was considered an upbeat, proactive-sounding word, evocative of a regaining of youth." Taken together with Ferring's previous instruction to sales representatives to use the term as a "buzz" word in their sales pitches, the panel's stated reasoning makes plain that the Report is designed to be more of a marketing piece than any serious clinical analysis.

- This same panel ultimately concluded that, of the exogenous HA products on the market, "only Euflexxa . . . has enough of those features" that resemble those of endogenous HA "to allow it to be discussed as best matching the BioRestorative profile."
- In reaching this conclusion, the panel evaluated each of the exogenous HA products, including Euflexxa, not by conducting or analyzing head-to-head clinical studies comparing these products, but rather by using an oversimplified process whereby each product was assessed based on its own characteristics. Notably, the measure by which the HA products were evaluated came down to five arbitrary features of endogenous HA (high molecular weight, structure, purity, minimal protein content and viscosity) that the panel itself selected. The panel then assigned scores to the exogenous HA products based on how well those products approximated these particular features of endogenous HA. Not surprisingly, the five features handpicked by the Ferring-sponsored panel most closely resembled those found in Euflexxa.
- 191. Neither the highly subjective analysis nor the subsequent "conclusion" reached by Dr. Rosen and the panel are supported by any adequate, well-controlled studies in which products are compared head-to-head using comparable dosage regimens or by a single, large, well-controlled study. Nevertheless, Relator was instructed by his District Manager, Susan Schwartz, to use the flimsy BioRestorative Report in his interactions with physicians despite the Report's many shortcomings. In fact, the Report is still available on the Institute for Clinical

Care website, which also receives its financial support from Ferring. *See* http://www.clincare.org/PDF/BioRestorativeProfilingMonograph.pdf (last visited Feb. 28, 2012).

- 192. Ferring also encouraged its sales force to support the Company's superiority claims by using the Kirchner Study, a Ferring-supported clinical trial used by the Company in its promotional efforts. Relator and other sales representatives were provided annotated versions of the clinical reprint prepared by Ferring that were to be used to highlight these superiority claims, as well as claims that Euflexxa was safer than other HA products. The Kirchner Study, however, was not designed to assess whether purity or high molecular weight were factors that established Euflexxa's effectiveness or safety over other HA products. Instead, the Kirchner Study was explicitly designed to test Euflexxa's non-inferiority to Synvisc®. In other words, in terms of efficacy, if Euflexxa was shown to be non-inferior to Synvisc®, that simply means that Euflexxa was on par with Synvisc® in the treatment of osteoarthritis.
- 193. Unencumbered by this fact, Ferring nevertheless used anecdotal evidence from the Kirchner Study as a foundation for its illegal superiority claims. In the Ferring-annotated version, sales representatives were trained to highlight the high molecular weight of Euflexxa (2.4—3.6 million Daltons) and to emphasize that this high molecular weight "is achieved by carefully controlling the fermentation, recovery and purification processes . . . that does not require any cross-linking processes" associated with avian-based HA products.
- 194. The sales force's use of the annotated Kirchner Study was the result of a Company-driven initiative. Specifically, in a January 7, 2010 Field Coaching Report—a evaluation tool used by Ferring to support the development of its sales representatives and establish best practices—Susan Schwartz, Relator's District Manager, identified as a "priority" that he "[c]ontinue practicing with Kirchner." Schwartz then added, "When I see you next we

will refine your messaging. Please review the Annotated Kirchner I gave you. That is a great resource!"

- 195. Ferring's superiority claims are unsupportable insofar as they are made in the complete absence of any clinical studies—much less any study designed to meet the rigorous standards established by the FDA for adequate and well-controlled clinical investigations. Despite this fact, Ferring's sales personnel were directed to (and did) regularly and proactively provide these superiority messages to doctors in violation of the relevant regulations proscribing such conduct.
- In violation of federal law, Ferring knowingly and deliberately falsely promoted Euflexxa by the use of unsubstantiated comparative claims, comparing Euflexxa to other HA products. These unsubstantiated, comparative claims are prohibited by the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 352 and 21 C.F.R. § 202.1(e)(6), as well as Ferring's own internal sales policies. The use of unsubstantiated comparative claims renders a device "misbranded" by the FDA. Ferring promoted these Euflexxa falsehoods to physicians to induce physicians to prescribe Euflexxa. Once Euflexxa became "misbranded" it was no longer eligible for reimbursement by Federal Programs, including Medicaid.
- 197. Additionally, Ferring was required to provide fair and balanced information whenever it engaged in promotional activities. Fair and balanced promotional activities include written materials as well as oral presentations. According to federal regulations and industry standards and practices, "fair and balanced" means that whenever Ferring made representations about Euflexxa's efficacy, it was required to also make statements about the device's side effects.

198. In violation of federal law, Ferring knowingly and deliberately failed to give fair and balanced presentations on Euflexxa. These false superiority claims about Euflexxa's superiority were made without "substantial evidence" to support such claims. As such, any statements about Euflexxa's superiority were false, misleading, distorted, inaccurate, unfair, imbalanced and omitted material facts Ferring was required to disclose. This fraudulent scheme resulted in the submission of false claims to Government Programs. *See* Exhibit A.

# X. FERRING VIOLATED ITS OBLIGATIONS UNDER THE FEDERAL ACQUISITION REGULATIONS SYSTEM

- 199. Ferring has sold (and continues to sell) a substantial amount of medical equipment to the Veterans Health Administration and other Government payors. Pursuant to the Federal Acquisition Regulations System ("FARS"), "[t]he Government will seek to obtain the offeror's best price (the best price given to the most favored customer)." *See* 48 C.F.R. § 538.270(a). The calculation of Best Price must include, *inter alia*, "[f]ree goods" the provision of which are "not contingent upon any purchase requirement." *See* 48 C.F.R. § 447.505 (d)(10). Ferring was aware of the FARS, and knew that its compliance with those regulations was required, but nonetheless violated those regulations when it failed to include the \$0 cost of the free samples it offered commercial customers as part of its "best price" calculation.
- 200. Ferring's "Best Price" is generally calculated to be inclusive of cash discounts, free goods, volume discounts, and rebates. Thus, Ferring was obligated to report to its Government customers the "free goods" or other discounts or rebates offered to its commercial customers, described herein.

## XI. FERRING CAUSED THE SUBMISSION OF FALSE CLAIMS TO GOVERNMENT PROGRAMS AND THE *QUI TAM* STATES.

- As described above, Ferring's fraudulent conduct resulted in the provision of multiple, large volume free doses of Euflexxa to its customers. These were not "samples" provided to educate physicians on whether Euflexxa would be beneficial to their patients' care, nor were they provided so that the physicians could simply "try" Euflexxa. Instead, Ferring delivered substantial volumes of Euflexxa as a quid pro quo for physicians' loyalty to the product and/or their efforts to persuade other physicians to purchase Euflexxa, thereby influencing prescribing or utilization decisions. Ferring knew that such favorable treatment would lead to greater numbers of prescriptions for its products, including prescriptions for Government Program beneficiaries, throughout the United States.
- 202. Ferring's "free" samples violate the Anti-Kickback Statute. *See* 42 U.S.C. § 1320a-7b(b). None of these physicians were billed or invoiced for these samples.
- 203. On every occasion in which Ferring or another entity sought reimbursement from a Government-funded health program for a device or procedure induced by Ferring's unlawful kickbacks, Ferring knew, or in reckless disregard of the truth should have known, that a false claim was being submitted, and therefore caused that false claim to be submitted, and is itself liable for such false claim.
- 204. At all material times, Ferring knew that a substantial number of prescriptions written by physicians were written as a result of Ferring's fraudulent conduct and would be reimbursed by the Medicare and Medicaid programs.
- 205. Ferring's fraudulent conduct served its intended purpose, as it has induced physicians to write wasteful prescriptions for Euflexxa based on the Company's improper "superiority" marketing. Ferring has induced the submission of claims for reimbursement of

those prescriptions by Government Programs. The Government Programs did, in fact, reimburse those claims based on Ferring's illegal promotions.

206. Ferring has caused substantial prescriptions of Euflexxa to be written and submitted for reimbursement by Government Programs. The Government Programs did, in fact, reimburse those claims. *See* Exhibit A.

207. At least in part as a result of Defendants' illegal sales and marketing practices, Euflexxa has been heavily used for the treatment of Medicaid, Medicare Part D, and other Government Program participants.

### XII. FERRING VIOLATED THE FALSE CLAIMS ACT BY ITS FALSE CERTIFICATIONS OF COMPLIANCE WITH LAW

208. As described in this First Amended Complaint, Ferring caused physicians and pharmacies to falsely certify their compliance with applicable laws that require express and implied certifications of compliance with conditions of payment.

209. Ferring also caused physician-providers to falsely certify their compliance in connection with their receipt of kickbacks, including free samples of Euflexxa, in connection with Ferring's promotion of the medical device.

210. State Medicaid provider agreements include requirements that participating pharmacies and physician providers comply with all laws, rules, and regulations governing the Medicaid program, including compliance with the AKS. These agreements also include provisions that the pharmacies agree that the submittal of any claim by or on behalf of the pharmacy will constitute a certification that the medical services for which payment is claimed were furnished in accordance with the requirements of Medicaid, and that the information submitted in, with, or in support of the claim is true, accurate, and complete.

- 211. The Medicaid program expressly prohibits reimbursement for claims that are submitted as a result of kickbacks. As alleged in this First Amended Complaint, Ferring's illegal schemes caused the Medicaid-participating pharmacies and physician-providers to falsely certify their compliance with all laws, rules, and regulations governing the Medicaid program, including the antikickback laws, which prohibit an entity from knowingly and willingly offering, paying, soliciting, or receiving any remuneration to induce the referral of individuals or the purchase of items or services for which payment may be made under Medicare, Medicaid, or other federal or state health programs. These certifications were express, were a condition of payment or reimbursement by Government Programs, and were material to the Government's decision to pay or reimburse for Euflexxa.
- As to Medicare, physician-providers must sign agreements in which they agree to abide by all applicable Medicare laws and regulations, and certify their understanding that reimbursement of claims under Medicare is conditioned on compliance with the AKS. These certifications are also included in the claim forms themselves, *see*, *e.g.*, Forms CMS-855A and CMS855I. Thus, reimbursement for Medicare requires compliance with the Anti-Kickback Statute.
- 213. Ferring has, expressly and impliedly, falsely certified its compliance with these federal and state statutes and regulations.
- 214. Ferring's false certifications have directly caused Government Programs to pay or reimburse for prescriptions not eligible for payment or reimbursement.

#### COUNT I

#### (Violation of False Claims Act, 31 U.S.C. § 3729(a)(1); 31 U.S.C. § 3729(a)(1)(A))<sup>1</sup>

- 215. Relator incorporates herein by reference the preceding paragraphs of this First Amended Complaint as though fully set forth herein.
- 216. Defendants knowingly presented or caused to be presented, and may still be presenting or causing to be presented, to the Government false or fraudulent claims for payment or approval, in violation of 31 U.S.C. § 3729(a)(1); 31 U.S.C. § 3729(a)(1)(A).
- 217. As a result of Defendants' actions, as set forth above,, the United States of America has been, and may continue to be, severely damaged.

#### **COUNT II**

#### (Violation of False Claims Act, 31 U.S.C. § 3729(a)(2); 31 U.S.C. § 3729(a)(1)(B))<sup>2</sup>

- 218. Relator incorporates herein by reference the preceding paragraphs of this First Amended Complaint as though fully set forth herein.
- Defendants knowingly made, used, or caused to be made or used, and may still be making, using, or causing to be made or used, false or fraudulent records or statements material to the payment of false or fraudulent claims, in violation of 31 U.S.C. § 3729(a)(2); 31 U.S.C. § 3729(a)(1)(B).
- 220. The United States, unaware of the falsity of the claims and/or statements made by Defendants, and in reliance on the accuracy of these claims and/or statements, paid and may continue to be paying or reimbursing for Euflexxa prescribed to patients enrolled in Federal Programs.

<sup>&</sup>lt;sup>1</sup> To the extent wrongdoing occurred after May 20, 2009, this First Amended Complaint should be deemed to include violations of the Federal False Claims Act's recent amendments.

<sup>&</sup>lt;sup>2</sup> To the extent wrongdoing occurred after May 20, 2009, this First Amended Complaint should be deemed to include violations of the Federal False Claims Act's recent amendments.

America has been, and may continue to be, severely damaged.

# $\frac{COUNT~III}{\text{(Violation of False Claims Act, 31 U.S.C. § 3729(a)(3); 31 U.S.C. § 3729(a)(1)(C))}^3$

- 222. Relator incorporates herein by reference the preceding paragraphs of this First Amended Complaint as though fully set forth herein.
- As detailed above, Defendants knowingly conspired, and may still be conspiring, with health care professionals identified and described herein to commit acts, in violation of 31 U.S.C. §§ 3729(a)(1) & (a)(2); 31 U.S.C. §§ 3729(a)(1)(A) & (a)(1)(B). Defendants and these health care professionals committed overt acts in furtherance of the conspiracy as described above.
- As a result of Defendants' actions, as set forth above, the United States of America has been, and may continue to be, severely damaged.

# COUNT IV (Violation of False Claims Act, 31 U.S.C. § 3730(h))

- 225. Relator incorporates herein by reference the preceding paragraphs of this First Amended Complaint as though fully set forth herein.
- 226. As a result of Relator's lawful acts in furtherance of protected activities in the investigation and reporting of fraud, Defendants retaliated against Relator.
- 227. Relator's termination of employment was a direct result of Defendants' retaliatory acts, causing Relator to suffer, and continue to suffer, substantial financial and emotional damage in an amount to be proven at trial.

<sup>&</sup>lt;sup>3</sup> To the extent wrongdoing occurred after May 20, 2009, this First Amended Complaint should be deemed to include violations of the Federal False Claims Act's recent amendments.

#### **COUNT V**

#### (Violation of New Jersey Conscientious Employee Protection Act, N.J. Stat. Ann. § 34:19-1 et seq.)

- 228. Relator incorporates herein by reference the preceding paragraphs of the First Amended Complaint as though full set forth herein.
- As described above, Relator was directed by his District Manager, Susan Schwartz, to increase sales of Euflexxa by (i) providing large amounts of free samples to induce physicians to prescribe greater quantities of Euflexxa; (ii) "marketing the spread" between what physicians paid for the product and what they ultimately were reimbursed for by Medicare; and (iii) making illegal "superiority" claims regarding Euflexxa.
- 230. Relator reasonably believed that the above practices were in violation of company policy and federal and state law and reported the illegal conduct through both written and verbal communications to Ferring's Chief Compliance Officer, Jean Frydman. Following this disclosure, Relator afforded the Company a reasonable opportunity to investigate and correct the unlawful activities. In fact, Ferring conducted a compliance investigation that ultimately confirmed his allegations.
- 231. By reporting the violations to Ms. Frydman and Ferring, Relator was plainly performing a whistle-blowing activity protected under the New Jersey Conscientious Employee Protection Act, N.J. Stat. Ann. § 34:19-1 *et seq*.
- 232. Ferring took adverse employment action against Relator in the form of his termination, and a strong causal relationship exists between his termination and his whistle-blowing activity.
- 233. Defendants illegally terminated Relator in direct retaliation for his having reported the Company's unlawful activities in relation to the sales and marketing of Euflexxa,

causing Relator to suffer, and continue to suffer, substantial financial and emotional damage in an amount to be proven at trial.

#### <u>COUNT VI</u> (Violation of California False Claims Act)

- 234. Relator incorporates herein by reference the preceding paragraphs of this First Amended Complaint as though fully set forth herein.
- 235. This is a civil action brought by Relator, on behalf of the State of California, against Defendants under the California False Claims Act, Cal. Gov't Code § 12652(c).
- 236. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly presented, or caused to be presented, and may still be presenting or causing to be presented, false or fraudulent claims for payment or approval, in violation of Cal. Gov't Code § 12651(a)(1).
- Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements material to false or fraudulent claims, in violation of Cal. Gov't Code § 12651(a)(2).
- Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money to the State of California, or its political subdivisions, in violation of Cal. Gov't Code § 12651(a)(7).

- 239. The State of California, or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendants, and in reliance on the accuracy of these claims and/or statements, paid, and may continue to pay, for prescription drugs and prescription drug-related management services for recipients of state and state subdivision funded health insurance programs.
- 240. As a result of Defendants' actions as set forth above, the State of California and/or its political subdivisions have been, and may continue to be, severely damaged.

### COUNT VII (Violation of Colorado Medicaid False Claims Act)

- 241. Relator incorporates herein by reference the preceding paragraphs of this First Amended Complaint as though fully set forth herein.
- 242. This is a civil action brought by Relator, on behalf of the State of Colorado, against Defendants under the Colorado Medicaid False Claims Act, Colo. Rev. Stat. § 25.5-4-306(2).
- Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly presented, or caused to be presented, and may still be presenting or causing to be presented, to an officer or employee of the State of Colorado, or its political subdivisions, false or fraudulent claims for payment or approval, in violation of Colo. Rev. Stat. § 25.5-4-305(a).
- Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements material to false or fraudulent claims, in violation of Colo. Rev. Stat. § 25.5-4-305(b).

- Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money to the State of Colorado, or its political subdivisions, in violation of Colo. Rev. Stat. § 25.5-4-305(f).
- 246. The State of Colorado, or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendants, and in reliance on the accuracy of these claims and/or statements, paid, and may continue to pay, for prescription drugs and prescription drug-related management services for recipients of state and state subdivision funded health insurance programs.
- 247. As a result of Defendants' actions as set forth above, the State of Colorado and/or its political subdivisions have been, and may continue to be, severely damaged.

# **COUNT VIII**(Violation of Connecticut False Claims Act for Medical Assistance Programs)

- 248. Relator incorporates herein by reference the preceding paragraphs of this First Amended Complaint as though fully set forth herein.
- 249. This is a civil action brought by Relator, on behalf of the State of Connecticut, against Defendants under the Connecticut False Claims Act for Medical Assistance Programs, Conn. Gen. Stat. § 17b-301d.
- 250. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly presented, or caused to be presented, and may still be presenting or causing to be presented, to an officer or employee of the State of Connecticut, or its political subdivisions, false or fraudulent

claims for payment or approval under a medical assistance program administered by the Department of Social Services, in violation of Conn. Gen. Stat. § 17b-301b(1).

- Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements to secure the payment or approval by the State of Connecticut, or its political subdivisions, false or fraudulent claims under a medical assistance program administered by the Department of Social Services, in violation of Conn. Gen. Stat. § 17b-301b(2).
- Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money to the State of Connecticut, or its political subdivisions, under a medical assistance program administered by the Department of Social Services, in violation of Conn. Gen. Stat. § 17b-301b(7).
- 253. The State of Connecticut, or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendants, and in reliance on the accuracy of these claims and/or statements, paid, and may continue to pay, for prescription drugs and prescription drug-related management services for recipients of state and state subdivision funded health insurance programs.
- 254. As a result of Defendants' actions as set forth above, the State of Connecticut and/or its political subdivisions have been, and may continue to be, severely damaged.

### **COUNT IX**

## (Violation of Delaware False Claims and Reporting Act)

- 255. Relator incorporates herein by reference the preceding paragraphs of this First Amended Complaint as though fully set forth herein.
- 256. This is a civil action brought by of Relator, on behalf of the State of Delaware, against Defendants under the Delaware False Claims and Reporting Act, Del. Code Ann. tit. 6, § 1203(b).
- 257. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly presented or caused to be presented, and may still be presenting or causing to be presented, to an officer or employee of the State of Delaware, or its political subdivisions, false or fraudulent claims for payment or approval, in violation of Del. Code Ann. tit. 6, § 1201(a)(1).
- 258. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements to get false or fraudulent claims paid or approved by the State of Delaware, or its political subdivisions, in violation of Del. Code Ann. tit. 6, § 1201(a)(2).
- Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money to the State of Delaware, or its political subdivisions, in violation of Del. Code Ann. tit. 6, § 120l(a)(7).

- 260. The State of Delaware, or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendants, and in reliance on the accuracy of these claims and/or statements, paid, and may continue to pay, for prescription drugs and prescription drug-related management services for recipients of healthcare programs funded by the State of Delaware.
- 261. As a result of Defendants' actions, as set forth above, the State of Delaware and/or its political subdivisions have been, and may continue to be, severely damaged.

# **<u>COUNT X</u>** (Violation of District of Columbia False Claims Act)

- 262. Relator incorporates herein by reference the preceding paragraphs of this First Amended Complaint as though fully set forth herein.
- 263. This is a civil action brought by Relator, on behalf of the District of Columbia, against Defendants under the District of Columbia False Claims Act, D.C. Code § 2-308.15(b).
- Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly presented, or caused to be presented, and may still be presenting or causing to be presented, to an officer or employee of the District, or its political subdivisions, false or fraudulent claims for payment or approval, in violation of D.C. Code § 2-308.14(a)(l).
- Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and may still be making, using, or causing to be made or used, false records or statements to get false claims paid or approved by the District, or its political subdivisions, in violation of D.C. Code § 2-308.14(a)(2).

- Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and may still be making, using, or causing to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money to the District, or its political subdivisions, in violation of D.C. Code § 2-308.14(a)(7).
- 267. The District of Columbia, or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendants, and in reliance upon the accuracy of these claims and/or statements, paid, and may continue to pay, for prescription drugs and prescription drug-related management services for recipients of health insurance programs funded by the District.
- 268. As a result of Defendants' actions, as set forth above, the District of Columbia and/or its political subdivisions have been, and may continue to be, severely damaged.

# **COUNT XI**(Violation of Florida False Claims Act)

- 269. Relator incorporates herein by reference the preceding paragraphs of this First Amended Complaint as though fully set forth herein.
- 270. This is a civil action brought by Relator, on behalf of the State of Florida, against Defendants under the Florida False Claims Act, Fla. Stat. § 68.083(2).
- 271. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly presented or caused to be presented, and may still be presenting or causing to be presented, to an officer or employee of the State of Florida, or its agencies, false or fraudulent claims for payment or approval, in violation of Fla. Stat. § 68.082(2)(a).

- Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements to get false or fraudulent claims paid or approved by the State of Florida, or its agencies, in violation of Fla. Stat. § 68.082(2)(b).
- 273. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money to the State of Florida, or its agencies, in violation of Fla. Stat. § 68.082(2)(g).
- 274. The State of Florida, or its agencies, unaware of the falsity of the claims and/or statements made by Defendants, and in reliance on the accuracy of these claims and/or statements, paid, and may continue to pay, for prescription drugs and prescription drug-related management services for recipients of health insurance plans funded by the State of Florida or its agencies.
- 275. As a result of Defendants' actions, as set forth above, the State of Florida and/or its agencies have been, and may continue to be, severely damaged.

## <u>COUNT XII</u> (Violation of Georgia False Medicaid Claims Act)

- 276. Relator incorporates herein by reference the preceding paragraphs of this First Amended Complaint as though fully set forth herein.
- 277. This is a civil action brought by Relator, on behalf of the State of Georgia, against Defendants pursuant to the Georgia False Medicaid Claims Act, Ga. Code Ann. § 49-4-168.2(b).

- 278. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly presented or caused to be presented, and may still be presenting or causing to be presented, to the Georgia Medicaid program false or fraudulent claims for payment or approval, in violation of Ga. Code Ann. § 49-4-168.1(a)(1).
- 279. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements to get false or fraudulent claims paid or approved by the Georgia Medicaid program, in violation of Ga. Code Ann. § 49-4-168.1(a)(2).
- 280. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money to the State of Georgia, or its political subdivisions, in violation of Ga. Code Ann. § 49-4-168.1(a)(7).
- 281. The State of Georgia, or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendants, and in reliance on the accuracy of these claims and/or statements, paid, and may continue to pay, for prescription drugs and prescription drug-related management services for recipients of Medicaid.
- 282. As a result of Defendants' actions, as set forth above, the State of Georgia and/or political subdivisions have been, and may continue to be, severely damaged.

### **COUNT XIII**

## (Violation of Hawaii False Claims Act)

- 283. Relator incorporates herein by reference the preceding paragraphs of this First Amended Complaint as though fully set forth herein.
- 284. This is a civil action brought by Relator, on behalf of the State of Hawaii, against Defendants under the Hawaii False Claim Act, Haw. Rev. Stat. § 661-25.
- Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly presented or caused to be presented, and may still be presenting or causing to be presented, to an officer or employee of the State of Hawaii, or its political subdivisions, false or fraudulent claims for payment or approval, in violation of Haw. Rev. Stat. § 661-21(a)(l).
- Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used or caused to be made and used, and may still be making, using or causing to be made or used, false records or statements to get false or fraudulent claims paid or approved by the State of Hawaii, or its political subdivisions, in violation of Haw. Rev. Stat. § 661-21(a)(2).
- Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money to the State of Hawaii, or its political subdivisions, in violation of Haw. Rev. Stat. § 661-21(a)(7).
- 288. The State of Hawaii, or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendants, and in reliance upon the accuracy of these claims

and/or statements, paid, and may continue to pay, for prescription drugs and prescription drugrelated management services for recipients of state funded health insurance programs.

289. As a result of Defendants' actions, as set forth above, the State of Hawaii and/or its political subdivisions have been, and may continue to be, severely damaged.

# COUNT XIV (Violation of Illinois False Claims Act)

- 290. Relator incorporates herein by reference the preceding paragraphs of this First Amended Complaint as though fully set forth herein.
- 291. This is a civil action brought by Relator, on behalf of the State of Illinois, against Defendants under the Illinois False Claims Act, 740 Ill. Comp. Stat. 175/4(b).
- 292. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly presented, or caused to be presented, and may still be presenting or causing to be presented, false or fraudulent claims for payment or approval, in violation of 740 Ill. Comp. Stat. 175/3(a)(1)(A).
- 293. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and may still be making, using, or causing to be made or used, false record or statements material to get false or fraudulent claims paid or approved by the State of Illinois, or its political subdivisions, in violation of 740 Ill. Comp. Stat. 175/3(a)(1)(B).
- 294. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and may still be making, using, or causing to be made or used, false records or statements material to conceal, avoid or decrease an obligation to pay or

transmit money to the State of Illinois, or its political subdivisions, in violation of 740 Ill. Comp. Stat. 175/3(a)(1)(G).

- 295. The State of Illinois, or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendants, and in reliance on the accuracy of those claims and/or statements, paid, and may continue to pay, for prescription drugs and prescription drug-related management services for recipients of state funded health insurance programs.
- 296. As a result of Defendants' actions, as set forth above, the State of Illinois and/or its political subdivisions have been, and may continue to be, severely damaged.

## <u>COUNT XV</u> (Violation of Indiana False Claims and Whistleblower Protection Act)

- 297. Relator incorporates herein by reference the preceding paragraphs of this First Amended Complaint as though fully set forth herein.
- 298. This is a civil action brought by Relator, on behalf of the State of Indiana, against Defendants under the Indiana False Claims and Whistleblower Protection Act, Ind. Code § 5-11-5.5-4(a).
- 299. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly or intentionally presented, or caused to be presented, and may still be presenting or causing to be presented, false claims to the State of Indiana, or its political subdivisions, for payment or approval, in violation of Ind. Code § 5-11-5.5-2(b)(l).
- 300. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly or intentionally made, used, or caused to be made or used, and may still be making, using, or causing to be made or used, false records or statements to obtain payment or approval of false

claims from the State of Indiana, or its political subdivisions, in violation of Ind. Code § 5-11-5.5-2(b)(2).

- 301. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly or intentionally made, used, or caused to be made or used, and may still be making, using, or causing to be made or used, false records or statements to avoid an obligation to pay or transmit money to the State of Indiana, or its political subdivisions, in violation of Ind. Code § 5-11-5.5-2(b)(6).
- 302. The State of Indiana, or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendants, and in reliance on the accuracy of those claims and/or statements, paid, and may continue to pay, for prescription drugs and prescription drug-related management services for recipients of state funded health insurance programs.
- 303. As a result of Defendants' actions, as set forth above, the State of Indiana and/or its political subdivisions have been, and may continue to be, severely damaged.

# COUNT XVI (Violation of Iowa False Claims Act)

- 304. Relator incorporates herein by reference the preceding paragraphs of this First Amended Complaint as though fully set forth herein.
- 305. This is a civil action brought by Relator, on behalf of the State of Iowa, against Defendants under the Iowa False Claims Act, Iowa Code § 685.3(2)(a).
- 306. Defendants, in reckless disregard or deliberate ignorance for the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly presented, or caused to be presented, and may still be presenting or causing to be presented, false or fraudulent claims for payment or approval, in violation of Iowa Code § 685.2(1)(a).

- 307. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements material to false or fraudulent claims, in violation of Iowa Code § 685.2(1)(b).
- 308. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and may still me making, using or causing to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money to the State of Iowa, or its political subdivisions, in violation of Iowa Code § 685.2(1)(g).
- 309. The State of Iowa, or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendants, and in reliance on the accuracy of these claims and/or statements, paid for prescription drugs and prescription drug-related management services for recipients of health insurance programs funded by the state or its political subdivisions.
- 310. As a result of Defendants' actions, as set forth above, the State of Iowa and/or its political subdivisions have been, and may continue to be, severely damaged.

## <u>COUNT XVII</u> (Violation of Louisiana Medical Assistance Programs Integrity Law)

- 311. Relator incorporates herein by reference the preceding paragraphs of this First Amended Complaint as though fully set forth herein.
- 312. This is a civil action brought by Relator, on behalf of the State of Louisiana's medical assistance programs, against Defendants under the Louisiana Medical Assistance Programs Integrity Law, La. Rev. Stat. Ann. § 46:439.1.

- 313. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly presented, or caused to be presented, and may still be presenting or causing to be presented, false or fraudulent claims, in violation of La. Rev. Stat. Ann. § 46:438.3(A).
- Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly engaged in misrepresentation, and may still be engaging in misrepresentation, to obtain, or attempt to obtain, payment from medical assistance programs funds, in violation of La. Rev. Stat. Ann. § 46:438.3(B).
- 315. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly submitted, and may continue to submit, claims for goods, services or supplies which were medically unnecessary or which were of substandard quality or quantity, in violation of La. Rev. Stat. Ann. § 46:438.3(D).
- 316. The State of Louisiana, its medical assistance programs, political subdivisions and/or the Department, unaware of the falsity of the claims and/or statements made by Defendants, or their actions as set forth above, acted in reliance, and may continue to act in reliance, on the accuracy of Defendants' claims and/or statements in paying for prescription drugs and prescription drug-related management services for medical assistance program recipients.
- 317. As a result of Defendants' actions, as set forth above, the State of Louisiana, its medical assistance programs, political subdivisions and/or the Department have been, and may continue to be, severely damaged.

### **COUNT XVIII**

## (Violation of Maryland False Health Claims Act)

- 318. Relator incorporates herein by reference the preceding paragraphs of this First Amended Complaint as though fully set forth herein.
- 319. This is a civil action brought by Relator, on behalf of the State of Maryland, against Defendants under the Maryland False Health Claims Act of 2010, Md. Code Ann., Health-Gen. § 2-604.
- 320. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly presented or caused to be presented, and may still be presenting or causing to be presented, false or fraudulent claims for payment or approval, in violation of Md. Code Ann., Health-Gen. § 2-602(a)(1).
- 321. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements material to false or fraudulent claims, in violation of Md. Code Ann., Health-Gen. § 2-602(a)(2).
- 322. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and may still me making, using or causing to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money to the State of Maryland, or its political subdivisions, in violation of Md. Code Ann., Health-Gen. § 2-602(a)(8).

- 323. The State of Maryland, or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendants, and in reliance on the accuracy of these claims and/or statements, paid for prescription drugs and prescription drug-related management services for recipients of health insurance programs funded by the state or its political subdivisions.
- 324. As a result of Defendants' actions, as set forth above, the State of Maryland and/or its political subdivisions have been, and may continue to be, severely damaged.

### **COUNT XIX**

### (Violation of Massachusetts False Claims Act)

- 325. Relator incorporates herein by reference the preceding paragraphs of this First Amended Complaint as though fully set forth herein.
- 326. This is a civil action brought by Relator, on behalf of the Commonwealth of Massachusetts, against Defendants under the Massachusetts False Claims Act, Mass. Gen. Laws ch. 12 § 5C(2).
- 327. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly presented or caused to be presented, and may still be presenting or causing to be presented, false or fraudulent claims for payment or approval, in violation of Mass. Gen. Laws ch. 12 § 5B(1).
- Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements to obtain payment or approval of claims by the Commonwealth of Massachusetts, or its political subdivisions, in violation of Mass. Gen. Laws ch. 12 § 5B(2).

- 329. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money to the Commonwealth of Massachusetts, or its political subdivisions, in violation of Mass. Gen. Laws ch. 12 § 5B(8).
- 330. The Commonwealth of Massachusetts, or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendants, and in reliance on the accuracy of these claims and/or statements, paid, and may continue to pay, for prescription drugs and prescription drug-related management services for recipients of health insurance programs funded by the state or its political subdivisions.
- 331. As a result of Defendants' actions, as set forth above, the Commonwealth of Massachusetts and/or its political subdivisions have been, and may continue to be, severely damaged.

# **COUNT XX**(Violation of Michigan Medicaid False Claims Act)

- 332. Relator incorporates herein by reference the preceding paragraphs of this First Amended Complaint as though fully set forth herein.
- 333. This is a civil action brought by Relator, on behalf of the State of Michigan, against Defendants under the Michigan Medicaid False Claims Act, Mich. Comp. Laws § 400.610a(1).
- 334. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made or caused to be made, and may still be making or causing to be made, false statements or

false representations of material facts in an application for Medicaid benefits, in violation of Mich. Comp. Laws § 400.603(1).

- 335. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made or caused to be made false statements or false representations of a material fact for use in determining rights to a Medicaid benefit, in violation of Mich. Comp. Laws § 400.603(2).
- 336. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly concealed or failed to disclose, and may still be concealing or failing to disclose, an event affecting its initial or continued right to receive a Medicaid benefit, or the initial or continued right of any other person on whose behalf Defendants has applied for or is receiving a benefit with intent to obtain a benefit to which Defendants were not entitled or in an amount greater than that to which Defendants were entitled, in violation of Mich. Comp. Laws § 400.603(3).
- Of the nature of their conduct and that their conduct is substantially certain to cause the payment of a Medicaid benefit, knowingly made, presented or caused to be made or presented, and may still be presenting or causing to be presented, to an employee or officer of the State of Michigan, or its political subdivisions, false claims under the Social Welfare Act, Mich. Comp. Laws § 400.1-400.122, in violation of Mich. Comp. Laws § 400.607(1).
- 338. The State of Michigan, or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendants, and in reliance on the accuracy of these claims and/or statements, paid, and may continue to pay, for prescription drugs and prescription drugs related management services for recipients of Medicaid.

339. As a result of Defendants' actions, as set forth above, the State of Michigan and/or its political subdivisions have been, and may continue to be, severely damaged.

# COUNT XXI (Violation of Minnesota False Claims Act)

- 340. Relator incorporates herein by reference the preceding paragraphs of this First Amended Complaint as though fully set forth herein.
- 341. This is a civil action brought by Relator, on behalf of the State of Minnesota, against Defendants under the Minnesota False Claims Act, Minn. Stat. § 15C.05(a).
- 342. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly presented or caused to be presented, and may still be presenting or causing to be presented, to an officer or employee of the State of Minnesota, or its political subdivisions, false or fraudulent claims for payment or approval, in violation of Minn. Stat. § 15C.02(a)(1).
- 343. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements to get false or fraudulent claim paid or approved by the State of Minnesota, or its political subdivisions, in violation of Minn. Stat. § 15C.02(a)(2).
- Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money to the State of Minnesota, or its political subdivisions, in violation of Minn. Stat. § 15C.02(a)(7).

- 345. The State of Minnesota, or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendants, and in reliance on the accuracy of these claims and/or statements, paid, and may continue to pay, for prescription drugs and prescription drug-related management services for recipients of state and state subdivision funded health insurance programs.
- 346. As a result of Defendants' actions, as set forth above, the State of Minnesota and/or its political subdivisions have been, and may continue to be, severely damaged.

## COUNT XXII (Violation of Montana False Claims Act)

- 347. Relator incorporates herein by reference the preceding paragraphs of this First Amended Complaint as though fully set forth herein.
- 348. This is a civil action brought by Relator, on behalf of the State of Montana against, Defendants under the Montana False Claims Act, Mont. Code Ann. § 17-8-406(1).
- 349. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly presented or caused to be presented, and may still be presenting or causing to be presented, to an officer or employee of the State of Montana, or its political subdivisions, false or fraudulent claims for payment or approval, in violation of Mont. Code Ann. § 17-8-403(1)(a).
- 350. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements to get false or fraudulent claims paid or approved by the State of Montana, or its political subdivisions, in violation of Mont. Code Ann. § 17-8-403(1)(b).

- 351. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money to the State of Montana, or its political subdivisions, in violation of Mont. Code Ann. § 17-8-403(1)(g).
- 352. The State of Montana, or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendants, and in reliance on the accuracy of these claims and/or statements, paid, and may continue to pay, for prescription drugs and prescription drug-related management services for recipients of health insurance programs funded by the state or its political subdivisions.
- 353. As a result of Defendants' actions, as set forth above, the State of Montana and/or its political subdivisions have been, and may continue to be, severely damaged.

# COUNT XXIII (Violation of Nevada False Claims Act)

- 354. Relator incorporates herein by reference the preceding paragraphs of this First Amended Complaint as though fully set forth herein.
- 355. This is a civil action brought by Relator, on behalf of the State of Nevada, against Defendants under the Nevada False Claims Act, Nev. Rev. Stat. § 357.080(1).
- 356. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly presented or caused to be presented, and may still be presenting or causing to be presented, false claims for payment or approval, in violation of Nev. Rev. Stat. § 357.040(1)(a).

- 357. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements to obtain payment or approval of false claims, in violation of Nev. Rev. Stat. § 357.040(1)(b).
- 358. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money to the State of Nevada, or its political subdivisions, in violation of Nev. Rev. Stat. § 357.040(1)(g).
- 359. The State of Nevada, or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendants, and in reliance on the accuracy of these claims and/or statements, paid, and may continue to pay, for prescription drugs and prescription drug-related management services for recipients of health insurance programs funded by the state or its political subdivisions.
- 360. As a result of Defendants' actions, as set forth above, the State of Nevada and/or its political subdivisions have been, and may continue to be, severely damaged.

# COUNT XXIV (Violation of New Jersey False Claims Act)

- 361. Relator incorporates herein by reference the preceding paragraphs of this First Amended Complaint as though fully set forth herein.
- 362. This is a civil action brought by Relator, on behalf of the State of New Jersey, against Defendants pursuant to the New Jersey False Claims Act, N.J. Stat. Ann. § 2A:32C-5(b).

- 363. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly or intentionally presented or caused to be presented, and may still be presenting or causing to be presented, to an employee, officer or agent of the State of New Jersey, or to any contractor, grantee, or other recipient of State funds, false or fraudulent claims for payment or approval, in violation of N.J. Stat. Ann. § 2A:32C-3(a).
- Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used or caused to made or used, and may still be making, using or causing to be made or used, false records or statements to get false or fraudulent claims paid or approved by the State of New Jersey, or its political subdivisions, in violation of N.J. Stat. Ann. § 2A:32C-3(b).
- Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money to the State of New Jersey, or its political subdivisions, in violation of N.J. Stat. Ann. § 2A:32C-3(g).
- 366. The State of New Jersey, or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendants, and in reliance on the accuracy of these claims and/or statements, paid, and may continue to pay, for prescription drugs and prescription drug-related management services for recipients of Medicaid.
- 367. As a result of Defendants' actions, as set forth above, the State of New Jersey and/or its political subdivisions have been, and may continue to be, severely damaged.

### **COUNT XXV**

### (Violation of New Mexico Medicaid False Claims Act)

- 368. Relator incorporates herein by reference the preceding paragraphs of this First Amended Complaint as though fully set forth herein.
- 369. This is a civil action brought by Relator, on behalf of the State of New Mexico, against Defendants under the New Mexico Medicaid False Claims Act, N.M. Stat. Ann. § 27-14-7(B).
- 370. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly presented or caused to be presented, and may still be presenting or causing to be presented, to the State of New Mexico, or its political subdivisions, false or fraudulent claims for payment under the Medicaid program, in violation of N.M. Stat. Ann. § 27-14-4(A).
- 371. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements to obtain false or fraudulent claims under the Medicaid program paid for or approved by the State of New Mexico, or its political subdivisions, in violation of N.M. Stat. Ann. § 27-14-4(C).
- 372. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money to the State of New Mexico, or its political subdivisions, relative to the Medicaid program, in violation of N.M. Stat. Ann. § 27-14-4(E).

- 373. The State of New Mexico, or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendants, and in reliance on the accuracy of these claims and/or statements, paid, and may continue to pay, for prescription drugs and prescription drug-related management services for recipients of health insurance programs funded by the state or its political subdivisions.
- 374. As a result of Defendants' actions, as set forth above, the State of New Mexico and/or its political subdivisions have been, and may continue to be, severely damaged.

## COUNT XXVI (Violation of New York False Claims Act)

- 375. Relator incorporates herein by reference the preceding paragraphs of this First Amended Complaint as though fully set forth herein.
- 376. This is a civil action brought by Relator, on behalf of the State of New York, against Defendants under the New York False Claims Act, N.Y. State Fin. Law § 190(2).
- 377. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly presented or caused to be presented, and may still be presenting or causing to be presented, false or fraudulent claims for payment or approval, in violation of N.Y. State Fin. Law § 189(1)(a).
- Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements material to false or fraudulent claims, in violation of N.Y. State Fin. Law § 189(1)(b).
- 379. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly

made, used, or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements material to an obligation to pay or transmit money to the State of New York, or its political subdivisions, in violation of N.Y. State Fin. Law § 189(1)(g).

- 380. The State of New York, or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendants, and in reliance on the accuracy of these claims and/or statements, paid, and may continue to pay, for prescription drugs and prescription drug-related management services for recipients of health insurance programs funded by the state or its political subdivisions.
- 381. As a result of Defendants' actions, set forth above, the State of New York and/or its political subdivisions have been, and may continue to be, severely damaged.

# **COUNT XXVII**(Violation of North Carolina False Claims Act)

- 382. Relator incorporates herein by reference the preceding paragraphs of this First Amended Complaint as though fully set forth herein.
- 383. This is a civil action brought by Relator, on behalf of the State of North Carolina, against Defendants under the North Carolina False Claims Act, N.C. Gen. Stat. § 1-608(b).
- Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly presented or caused to be presented, and may still be presenting or causing to be presented, false or fraudulent claims for payment or approval, in violation of N.C. Gen. Stat. § 1-607(a)(1).
- 385. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used or caused to be made or used, and may still be making, using or causing to be made

or used, false records or statements material to false or fraudulent claims, in violation of N.C. Gen. Stat. § 1-607(a)(2).

- Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money to the State of North Carolina, or its political subdivisions, in violation of N.C. Gen. Stat. § 1-607(a)(7).
- 387. The State of North Carolina, or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendants, and in reliance on the accuracy of these claims and/or statements, paid, and may continue to pay, for prescription drugs and prescription drug-related management services for recipients of health insurance programs funded by the state or its political subdivisions.
- 388. As a result of Defendants' actions, as set forth above, the State of North Carolina and/or its political subdivisions have been, and may continue to be, severely damaged.

# COUNT XXVIII (Violation of Oklahoma Medicaid False Claims Act)

- 389. Relator incorporates herein by reference the preceding paragraphs of this First Amended Complaint as though fully set forth herein.
- 390. This is a civil action brought by Relator, on behalf of the State of Oklahoma, against Defendants pursuant to the Oklahoma Medicaid False Claims Act, Okla. Stat. tit. 63, § 5053.2(B)(1).
- 391. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly

presented or caused to be presented, and may still be presenting or causing to be presented, to an officer or employee of the State of Oklahoma, or its political subdivisions, false or fraudulent claims for payment or approval, in violation of Okla. Stat. tit. 63, § 5053.1(B)(1).

- 392. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made or caused to be made, and may still be making or causing to be made, false records or statements to get false or fraudulent claims paid or approved by the State of Oklahoma, or its political subdivisions, in violation of Okla. Stat. tit. 63, § 5053.1(B)(2).
- 393. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money to the State of Oklahoma, or its political subdivisions, in violation of Okla. Stat. tit. 63, § 5053.1(B)(7).
- 394. The State of Oklahoma, or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendants, and in reliance on the accuracy of these claims and/or statements, paid, and may continue to pay, for prescription drugs and prescription drug-related management services for recipients of Medicaid.
- 395. As a result of Defendants' actions, as set forth above, the State of Oklahoma and/or its political subdivisions have been, and may continue to be, severely damaged.

# COUNT XXIX (Violation of Rhode Island False Claims Act)

396. Relator incorporates herein by reference the preceding paragraphs of this First Amended Complaint as though fully set forth herein.

- 397. This is a civil action brought by Relator, on behalf of the State of Rhode Island, against Defendants pursuant to the Rhode Island False Claims Act, R.I. Gen. Laws § 9-1.1-4(b).
- 398. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly presented or caused to be presented, and may still be presenting or causing to be presented, to an officer or employee of the State of Rhode Island or a member of Rhode Island's National Guard, false or fraudulent claims for payment or approval, in violation of R.I. Gen. Laws § 9-1.1-3(a)(1).
- 399. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made or caused to be made, and may still be making or causing to be made, false records or statements to get false or fraudulent claims paid or approved by the State of Rhode Island, or its political subdivisions, in violation of R.I. Gen. Laws § 9-1.1-3(a)(2).
- 400. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money to the State of Rhode Island, or its political subdivisions, in violation of R.I. Gen. Laws § 9-1.1-3(a)(7).
- 401. The State of Rhode Island, or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendants, and in reliance on the accuracy of these claims and/or statements, paid, and may continue to pay, for prescription drugs and prescription drug-related management services for recipients of Medicaid.

402. As a result of Defendants' actions, as set forth above, the State of Rhode Island and/or its political subdivisions have been, and may continue to be, severely damaged.

### <u>COUNT XXX</u> (Violation of Tennessee Medicaid False Claims Act)

- 403. Relator incorporates herein by reference the preceding paragraphs of this First Amended Complaint as though fully set forth herein.
- 404. This is a civil action brought by Relator, on behalf of the State of Tennessee, against Defendants under the Tennessee Medicaid False Claims Act, Tenn. Code Ann. § 71-5-183(b).
- 405. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly presented or caused to be presented, and may still be presenting or causing to be presented, to the State of Tennessee, or its political subdivisions, false or fraudulent claims for payment under the Medicaid program, in violation of Tenn. Code Ann. § 71-5-182(a)(1)(A).
- 406. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used or caused to be made or used, and may still be making, using or causing to be made or used, false or fraudulent records or statements to get false or fraudulent claims under the Medicaid program paid for or approved by the State of Tennessee, or its political subdivisions, in violation of Tenn. Code Ann. § 71-5-182(a)(1)(B).
- 407. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and may still be making, using or causing to be made or used, false or fraudulent records or statements to conceal, avoid or decrease an obligation to

pay or transmit money to the State of Tennessee, or its political subdivisions, relative to the Medicaid program, in violation of Tenn. Code Ann. § 71-5-182(a)(1)(D).

- 408. The State of Tennessee, or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendants, and in reliance on the accuracy of these claims and/or statements, paid, and may continue to pay, for prescription drugs and prescription drug-related management services for recipients of the Medicaid program.
- 409. As a result of Defendants' actions, as set forth above, the State of Tennessee and/or its political subdivisions have been, and may continue to be, severely damaged.

## <u>COUNT XXXI</u> (Violation of Texas Medicaid Fraud Prevention Act)

- 410. Relator incorporates herein by reference the preceding paragraphs of this First Amended Complaint as though fully set forth herein.
- 411. This is a civil action brought by Relator, on behalf of the State of Texas against, Defendants under the Texas Medicaid Fraud Prevention Act, Tex. Hum. Res. Code Ann. § 36.101(a).
- Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made or caused to be made, and may still be making or causing to be made, false statements or misrepresentations of material fact that permitted Defendants to receive a benefit or payment under the Medicaid program that was not authorized or that was greater than the benefit or payment that was authorized, in violation of Tex. Hum. Res. Code Ann. § 36.002(1).
- 413. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly concealed or failed to disclose, or caused to be concealed or not disclosed and may still be

concealing or failing to disclose, or causing to be concealed or not disclosed — information that permitted Defendants to receive a benefit or payment under the Medicaid program that was not authorized or that was greater than the payment that was authorized, in violation of Tex. Hum. Res. Code Ann. § 36.002(2).

- Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, caused to be made, induced or sought to induce, and may still be making, causing to be made, inducing or seeking to induce, false statements or misrepresentations of material fact concerning information required to be provided by a federal or state law, rule, regulation or provider agreement pertaining to the Medicaid program, in violation of Tex. Hum. Res. Code Ann. § 36.002(4)(B).
- 415. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, and may still be making, claims under the Medicaid program for services or products that were inappropriate, in violation of Tex. Hum. Res. Code Ann. § 36.002(7)(C).
- 416. The State of Texas, or it political subdivisions, unaware of the falsity of the claims and/or statements made by Defendants, and in reliance on the accuracy of these claims and/or statements, paid, and may continue to pay, for prescription drugs and prescription drug-related management services for recipients of Medicaid.
- 417. As a result of Defendants' actions, as set forth above, the State of Texas and/or its political subdivisions have been, and may continue to be, severely damaged.

### **COUNT XXXII**

### (Violation of Virginia Fraud Against Taxpayers Act)

- 418. Relator incorporates herein by reference the preceding paragraphs of this First Amended Complaint as though fully set forth herein.
- 419. This is a civil action brought by Relator, on behalf of the Commonwealth of Virginia, against Defendants under the Commonwealth of Virginia Fraud Against Taxpayers Act, Va. Code Ann. § 8.01-216.5(A).
- 420. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly presented or caused to be presented, and may still be presenting or causing to be presented, to an officer or employee of the Commonwealth of Virginia, or its political subdivisions, false or fraudulent claims for payment or approval, in violation of Va. Code Ann. § 8.01-216.3(A)(1).
- Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements to get false or fraudulent claims paid or approved by the Commonwealth of Virginia, or its political subdivisions, in violation of Va. Code Ann. § 8.01-216.3(A)(2).
- Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money to the Commonwealth of Virginia, or its political subdivisions, in violation of Va. Code Ann. § 8.01-216.3(A)(7).

- 423. The Commonwealth of Virginia, or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendants, and in reliance upon the accuracy of these claims and/or statements, paid, and may continue to pay, for prescription drugs and prescription drug-related management services for recipients of state funded health insurance programs.
- 424. As a result of Defendants' actions, as set forth above, the Commonwealth of Virginia and/or its political subdivisions have been, and may continue to be, severely damaged.

#### COUNT XXXIII

### (Violation of Wisconsin False Claims for Medical Assistance Law)

- 425. Relator incorporates herein by reference the preceding paragraphs of this First Amended Complaint as though fully set forth herein.
- 426. This is a civil action brought by Relator, on behalf of the State of Wisconsin, against Defendants under the Wisconsin False Claims for Medical Assistance Law, Wis. Stat. § 20.931(5)(a).
- 427. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly presented or caused to be presented, and may still be presenting or causing to be presented, to any officer, or employee, or agent of the State of Wisconsin, or its political subdivisions, false or fraudulent claims for medical assistance, in violation of Wis. Stat. § 20.931(2)(a).
- 428. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and may still be making, using, or causing to be made or used, false records or statements to obtain approval or payment of false claims for medical assistance, in violation of Wis. Stat. § 20.931(2)(b).

- 429. The State of Wisconsin, or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendants, and in reliance upon the accuracy of these claims and/or statements, paid, and may continue to pay, for prescription drugs and prescription drug-related management services for recipients of state funded health insurance programs.
- 430. As a result of Defendants' actions, as set forth above, the State of Wisconsin and/or its political subdivisions have been, and may continue to be, severely damaged.

### **WHEREFORE**, Relator prays for judgment against Defendants as follows:

- A. That Defendants be ordered to cease and desist from submitting any more false claims, or further violating 31 U.S.C. § 3729 et seq.; Cal. Gov't Code § 12650 et seq.; Colo. Rev. Stat. § 25.5-4-304 et seq.; Conn. Gen. Stat. § 17b-301a et seq.; Del. Code Ann. tit. 6, § 1201 et seq.; D.C. Code § 2-308.13 et seq.; Fla. Stat. § 68.081 et seq.; Ga. Code Ann. § 49-4-168 et seq.; Haw. Rev. Stat. § 661-21 et seq.; 740 III. Comp. Stat. § 175/1 et seq.; Ind. Code § 5-11-5.5 et seq.; Iowa Code § 685.1 et seq.; La. Rev. Stat. Ann. § 46:437.1 et seq.; Md. Code Ann., Health-Gen. § 2-601 et seq.; Mass. Gen. Laws ch. 12, § 5A et seq.; Mich. Comp. Laws § 400.601 et seq.; Minn. Stat. § 15C.01 et seq.; Mont. Code Ann. § 17-8-401 et seq.; Nev. Rev. Stat. § 357.010 et seq.; N.J. Stat. Ann. § 2A:32C-1 et seq.; N.M. Stat. Ann. § 27-14-1 et seq.; N.Y. State Fin. Law § 187 et seq.; N.C. Gen. Stat. § 1-605 et seq.; Okla. Stat. tit. 63, § 5053 et seq.; R.I. Gen. Laws § 9-1.1-1 et seq.; Tenn. Code Ann. § 71-5-181 et seq.; Tex. Hum. Res. Code Ann. § 36.001 et seq.; Va. Code Ann. § 8.01-216.1 et seq.; and Wis. Stat. § 20.931 et seq.
- B. That judgment be entered in Relator's favor and against Defendants in the amount of each and every false or fraudulent claim, multiplied as provided for in 31 U.S.C. § 3729(a), plus a civil penalty of not less than five thousand (\$5,000) or more than ten thousand dollars (\$10,000) per claim as provided by 31 U.S.C. § 3729(a), to the extent such multiplied penalties

shall fairly compensate the United States of America for losses resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;

- C. That Relator be awarded the maximum amount allowed pursuant to 31 U.S.C. §§ 3730(d) and 3730(h), Cal. Gov't Code § 12652(g)(4), Colo. Rev. Stat. § 25.5-4-306(4), Conn. Gen. Stat. § 17b-301e(e), Del. Code Ann. tit. 6, § 1205, D.C. Code § 2-308.15(f), Fla. Stat. § 68.085, Ga. Code Ann. § 49-4-168.2(i), Haw. Rev. Stat. § 661-27, 740 Ill. Comp. Stat. § 175/4(d), Ind. Code § 5-11-5.5-6, Iowa Code § 685.3(4)(a)(1); La. Rev. Stat. Ann. § 439.4, Md. Code Ann., Health-Gen. § 2-605, Mass. Gen. Laws ch.12, § 5F, Mich. Comp. Laws § 400.610a(9), Minn. Stat. § 15C.13, Mont. Code Ann. § 17-8-410, Nev. Rev. Stat. § 357.210, N.J. Stat. Ann. § 2A:32C-7, N.M. Stat. Ann. § 27-14-9, N.Y. State Fin. Law § 190(6), N.C. Gen. Stat. § 1-610, Okla. Stat. tit. 63, § 5053.4, R.I. Gen. Laws § 9-1.1-4(d), Tenn. Code Ann. § 71-5-183(d), Tex. Hum. Res. Code Ann. § 36.110, Va. Code Ann. § 8.01-216.7, and Wis. Stat. § 20.931(11), including without limitation (i) reinstatement of Relator's employment with no diminution of seniority, (ii) double back-pay for the period since Relator's unlawful retaliatory termination, (iii) interest on such back-pay for Relator, and (iv) special damages for Relator, including reasonable attorneys' fees and litigation costs.
- D. That judgment be entered in Relator's favor and against Defendants in the amount of the damages sustained by the State of California or its political subdivisions multiplied as provided for in Cal. Gov't Code § 12651(a), plus a civil penalty of not less than five thousand dollars (\$5,000) per claim or more than ten thousand dollars (\$10,000) per claim as provided by Cal. Gov't Code § 12651(a), to the extent such penalties shall fairly compensate the State of California or its political subdivisions for losses resulting from the various schemes undertaken

by Defendants, together with penalties for specific claims to be identified at trial after full discovery;

- E. That judgment be entered in Relator's favor and against Defendants in the amount of the damages sustained by the State of Colorado or its political subdivisions multiplied as provided for in Colo. Rev. Stat. § 25.5-4-305(1), plus a civil penalty of not less than five thousand dollars (\$5,000) or more than ten thousand dollars (\$10,000) for each act as provided by Colo. Rev. Stat. § 25.5-4-305(1), to the extent such multiplied penalties shall fairly compensate the State of Colorado or its political subdivisions for losses resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;
- F. That judgment be entered in Relator's favor and against Defendants in the amount of the damages sustained by the State of Connecticut multiplied as provided for in Conn. Gen. Stat. § 17b-301b(b)(2), plus a civil penalty of not less than five thousand dollars (\$5,000) or more than ten thousand dollars (\$10,000) for each act in violation of the State of Connecticut False Claims Act, as provided by Conn. Gen. Stat. § 17b-301b(b)(1), to the extent such multiplied penalties shall fairly compensate the State of Connecticut for losses resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;
- G. That judgment be entered in Relator's favor and against Defendants in the amount of the damages sustained by the State of Delaware multiplied as provided for in Del. Code Ann. tit. 6, §1201(a), plus a civil penalty of not less than five thousand five hundred dollars (\$5,500) or more than eleven thousand dollars (\$11,000) for each act in violation of the Delaware False Claims and Reporting Act, as provided by Del. Code Ann. tit. 6, §1201(a), to the extent such

multiplied penalties shall fairly compensate the State of Delaware for losses resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;

- H. That judgment be entered in Relator's favor and against Defendants in the amount of the damages sustained by the District of Columbia, multiplied as provided for in D.C. Code § 2-308.14(a), plus a civil penalty of not less than five thousand dollars (\$5,000) or more than ten thousand dollars (\$10,000) for each false claim, and the costs of this civil action brought to recover such penalty and damages, as provided by D.C. Code § 2-308.14(a), to the extent such multiplied penalties shall fairly compensate the District of Columbia for losses resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;
- I. That judgment be entered in Relator's favor and against Defendants in the amount of the damages sustained by the State of Florida or its agencies multiplied as provided for in Fla. Stat. § 68.082(2), plus a civil penalty of not less than five thousand five hundred dollars (\$5,500) or more than eleven thousand dollars (\$11,000) for each false claim as provided by Fla. Stat. Ann. § 68.082(2), to the extent such multiplied penalties shall fairly compensate the State of Florida or its agencies for losses resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;
- J. That judgment be entered in Relator's favor and against Defendants in the amount of the damages sustained by the State of Georgia or its political subdivisions multiplied as provided for in Ga. Code Ann. § 49-4-168.1(a), plus a civil penalty of not less than five thousand five hundred dollars (\$5,500) or more than eleven thousand dollars (\$11,000) per false claim as provided by Ga. Code Ann. § 49-4-168.1(a), to the extent such multiplied penalties shall fairly

compensate the State of Georgia or its political subdivisions for losses resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;

- K. That judgment be entered in Relator's favor and against Defendants in the amount of the damages sustained by the State of Hawaii, multiplied as provided for in Haw. Rev. Stat. § 661-21(a), plus a civil penalty of not less than five thousand dollars (\$5,000) or more than ten thousand dollars (\$10,000) as provided by Haw. Rev. Stat. § 661-21(a), to the extent such multiplied penalties shall fairly compensate the State of Hawaii for losses resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;
- L. That judgment be entered in Relator's favor and against Defendants in the amount of the damages sustained by the State of Illinois, multiplied as provided for in 740 Ill. Comp. Stat. § 175/3(a)(1)(A), plus a civil penalty of not less than five thousand five hundred dollars (\$5,500) or more than eleven thousand dollars (\$11,000) as provided by 740 Ill. Comp. Stat. § 175/3(a)(1)(A), and the costs of this civil action as provided by 740 Ill. Comp. Stat. § 175/3(a)(1)(B), to the extent such penalties shall fairly compensate the State of Illinois for losses resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;
- M. That judgment be entered in Relator's favor and against Defendants in the amount of the damages sustained by the State of Indiana, multiplied as provided for in Ind. Code § 5-11-5.5-2(b), plus a civil penalty of at least five thousand dollars (\$5,000) as provided by Ind. Code § 5-11-5.5-2(b), to the extent such penalties shall fairly compensate the State of Indiana for

losses resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;

- N. That judgment be entered in Relator's favor and against Defendants in the amount of damages sustained by the State of Iowa, multiplied as provided for in Iowa Code § 685.2(1), plus a civil penalty of not less than five thousand dollars (\$5,000) and not more than ten thousand dollars (\$10,000), as provided by Iowa Code § 685.2(1), to the extent such multiplied penalties shall fairly compensate the State of Iowa or its political subdivisions for losses resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;
- O. That judgment be entered in Relator's favor and against Defendants in the amount of the damages sustained by Louisiana's medical assistance programs, multiplied as provided for in La. Rev. Stat. Ann. § 46:438.6(B)(2), plus a civil penalty of no more than ten thousand dollars (\$10,000) per violation or an amount equal to three times the value of the illegal remuneration, whichever is greater, as provided for by La. Rev. Stat. Ann. § 46:438.6(B)(1), plus up to ten thousand dollars (\$10,000) for each false or fraudulent claim, misrepresentation, illegal remuneration, or other prohibited act, as provided by La. Rev. Stat. Ann. § 46:438.6(C)(l)(a), plus payment of interest on the amount of the civil fines imposed pursuant to Subsection B of § 438.6 at the maximum legal rate provided by La. Civil Code Art. 2924 from the date the damage occurred to the date of repayment, as provided by La. Rev. Stat. Ann. § 46:438.6(C)(l)(b), to the extent such multiplied fines and penalties shall fairly compensate the State of Louisiana's medical assistance programs for losses resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;

- P. That judgment be entered in Relator's favor and against Defendants for restitution to the State of Maryland or its political subdivisions for the value of payments or benefits provided, directly or indirectly, as a result of Defendants' unlawful acts, as provided for in Md. Code Ann., Health-Gen. § 2-602(a), multiplied as provided for in Md. Code Ann., Health-Gen. § 2-602(b)(1)(ii), plus a civil penalty of not more than ten thousand dollars (\$10,000) for each false claim, pursuant to Md. Code Ann., Health-Gen. § 2-602(b)(1)(i), to the extent such penalties fairly compensate the State of Maryland or its political subdivisions for losses resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;
- Q. That judgment be entered in Relator's favor and against Defendants for restitution to the Commonwealth of Massachusetts or its political subdivisions in the amount of a civil penalty of not less than five thousand dollars (\$5,000) dollars and not more than ten thousand dollars (\$10,000), plus three times the amount of damages, including consequential damages, sustained by Massachusetts as the result of Defendants' actions, plus the expenses of the civil action brought to recover such penalties and damages, as provided by Mass. Gen. Laws ch 12. § 5B, to the extent such penalties shall fairly compensate the Commonwealth of Massachusetts or its political subdivisions for losses resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;
- R. That judgment be entered in Relator's favor and against Defendants for restitution to the State of Michigan or its political subdivisions for the value of payments or benefits provided as a result of Defendants' unlawful acts, plus a civil penalty of triple the amount of damages suffered by Michigan as a result of Defendants' unlawful conduct, as well as not less

than five thousand dollars (\$5,000) or more than ten thousand dollars (\$10,000) per claim, as provided by Mich. Comp. Laws § 400.612(1), as well as the costs incurred by both Michigan and Relator, as provided by §§ 400.610a(9) and 400.610b, in order to fairly compensate the State of Michigan or its political subdivisions for losses resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;

- S. That judgment be entered in Relator's favor and against Defendants for restitution to the State of Minnesota or its political subdivisions for the value of payments or benefits provided as a result of Defendants' unlawful acts, plus a civil penalty of triple the amount of damages suffered by Minnesota as a result of Defendants' unlawful conduct, as well as not less than five thousand five hundred dollars (\$5,500) or more than eleven thousand dollars (\$11,000) per claim, as provided by Minn. Stat. § 15C.02(a), as well as the costs incurred by both Michigan and Relator, as provided by Minn. Stat. § 15C.12, in order to fairly compensate Minnesota or its political subdivisions for losses resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;
- T. That judgment be entered in Relator's favor and against Defendants for restitution to the State of Montana or its political subdivisions for the value of payments or benefits provided, directly or indirectly, as a result of Defendants' unlawful acts, as provided for in Mont. Code Ann. § 17-8-403, multiplied as provided for in Mont. Code Ann. § 17-8-403(2), plus a civil penalty of not less than five thousand dollars (\$5,000) or more than ten thousand dollars (\$10,000) for each false claim, pursuant to Mont. Code Ann. § 17-8-403(2), to the extent such multiplied penalties shall fairly compensate the State of Montana or its political subdivisions for

losses resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;

- U. That judgment be entered in Relator's favor and against Defendants for restitution to the State of Nevada for the value of payments or benefits provided, directly or indirectly, as a result of Defendants' unlawful acts, as provided for in Nev. Rev. Stat. § 357.040, multiplied as provided for in Nev. Rev. Stat. § 357.040(1), plus a civil penalty of not less than five thousand dollars (\$5,000) or more than ten thousand dollars (\$10,000) for each act, pursuant to Nev. Rev. Stat. § 357.040(1), to the extent such multiplied penalties shall fairly compensate the State of Nevada for losses resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;
- V. That judgment be entered in Relator's favor and against Defendants in the amount of the damages sustained by the State of New Jersey or its political subdivisions multiplied as provided for in N.J. Stat. Ann. § 2A:32C-3, plus a civil penalty of not less than and not more than the civil penalties allowed under the federal False Claims Act (31 U.S.C. § 3729 et seq.) for each false or fraudulent claim, to the extent such multiplied penalties shall fairly compensate the State of New Jersey or its political subdivisions for losses resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;
- W. That judgment be entered in Relator's favor and against Defendants for restitution to the State of New Mexico or its political subdivisions for the value of payments or benefits provided, directly or indirectly, as a result of Defendants' unlawful acts, as provided for in N.M. Stat. Ann. § 27-14-4, multiplied as provided for in N.M. Stat. Ann. § 27-14-4, to the extent such multiplied penalties shall fairly compensate the State of New Mexico or its political subdivisions

for losses resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;

- X. That judgment be entered in Relator's favor and against Defendants for restitution to the State of New York or its political subdivisions for the value of payments or benefits provided, directly or indirectly, as a result of Defendants' unlawful acts, as provided for in N.Y. State Fin. Law § 189(1), multiplied as provided for in N.Y. State Fin. Law § 189(1), plus a civil penalty of not less than six thousand dollars (\$6,000) or more than twelve thousand dollars (\$12,000) for each false claim, pursuant to N.Y. State Fin. Law § 189(1), to the extent such multiplied penalties shall fairly compensate the State of New York or its political subdivisions for losses resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;
- Y. That judgment be entered in Relator's favor and against Defendants for restitution to the State of North Carolina for the value of payments or benefits provided, directly or indirectly, as a result of Defendants' unlawful acts, as provided for in N.C. Gen. Stat. § 1-607, multiplied as provided for in N.C. Gen. Stat. § 1-607(a), plus a civil penalty of not less than five thousand five hundred dollars (\$5,500) or more than eleven thousand dollars (\$11,000) as provided by N.C. Gen. Stat. § 1-607(a), to the extent such multiplied penalties shall fairly compensate the State of North Carolina for losses resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;
- Z. That judgment be entered in Relator's favor and against Defendants in the amount of the damages sustained by the State of Oklahoma or its political subdivisions multiplied as provided for in Okla. Stat. tit. 63, § 5053.1(B), plus a civil penalty of not less than five thousand

dollars (\$5,000) or more than ten thousand dollars (\$10,000) as provided by Okla. Stat. tit. 63, \$5053.1(B), to the extent such multiplied penalties shall fairly compensate the State of Oklahoma or its political subdivisions for losses resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;

AA. That judgment be entered in Relator's favor and against Defendants in the amount of the damages sustained by the State of Rhode Island or its political subdivisions multiplied as provided for in R.I. Gen. Laws § 9-1.1-3(a), plus a civil penalty of not less than five thousand dollars (\$5,000) or more than ten thousand dollars (\$10,000) per claim as provided by R.I. Gen. Laws § 9-1,1-3(a), to the extent such multiplied penalties shall fairly compensate the State of Rhode Island or its political subdivisions for losses resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;

BB. That judgment be entered in Relator's favor and against Defendants for restitution to the State of Tennessee for the value of payments or benefits provided, directly or indirectly, as a result of Defendants' unlawful acts, as provided for in Tenn. Code Ann. § 71-5-182, multiplied as provided for in Tenn. Code Ann. § 71-5-182(a)(l), plus a civil penalty of not less than five thousand dollars (\$5,000) or more than twenty-five thousand dollars (\$25,000) pursuant to Tenn. Code Ann. § 71-5-182(a)(l), to the extent such multiplied penalties shall fairly compensate the State of Tennessee for losses resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;

CC. That judgment be entered in Relator's favor and against Defendants for restitution to the State of Texas for the value of payments or benefits provided, directly or indirectly, as a

result of Defendants' unlawful acts, as provided for in Tex. Hum. Res. Code Ann. § 36.052(a), multiplied as provided for in Tex. Hum. Res. Code Ann. § 36.052(a)(4), the interest on the value of such payments or benefits at the prejudgment interest rate in effect on the day the payment or benefit was paid or received, for the period from the date the payment or benefit was paid or received to the date that restitution is made to the State of Texas, pursuant to Tex. Hum. Res. Code Ann. § 36.052(a)(2), plus a civil penalty of not less than five thousand dollars (\$5,000) or more than fifteen thousand dollars (\$15,000) for each unlawful act committed that resulted in injury to an elderly or disabled person, and of not less than one thousand dollars (\$1,000) or more than ten thousand dollars (\$10,000) for each unlawful act committed that did not result in injury to an elderly or disabled person, pursuant to Tex. Hum. Res. Code Ann. §§ 36.052(a)(3)(A) and (B), to the extent such multiplied penalties shall fairly compensate the State of Texas for losses resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;

DD. That judgment be entered in Relator's favor and against Defendants in the amount of the damages sustained by the Commonwealth of Virginia, multiplied as provided for in Va. Code Ann. § 8.01-216.3(A), plus a civil penalty of not less than five thousand five hundred dollars (\$5,500) or more than eleven thousand dollars (\$11,000) as provided by Va. Code Ann. § 8.01-216.3(A), to the extent such multiplied penalties shall fairly compensate the Commonwealth of Virginia for losses resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;

EE. That judgment be entered in Relator's favor and against Defendants in the amount of the damages sustained by the State of Wisconsin or its political subdivisions multiplied as

provided for in Wis. Stat. § 20.931(2), plus a civil penalty of not less than five thousand dollars (\$5,000) or more than ten thousand dollars (\$10,000) as provided by Wis. Stat. § 20.931(2), to the extent such multiplied penalties shall fairly compensate the State of Wisconsin or its political subdivisions for losses resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;

FF. That Defendants be ordered to disgorge all sums by which they have been enriched unjustly by their wrongful conduct;

That judgment be granted for Relator against Defendants for all costs, including, GG. but not limited to, court costs, expert fees and all attorneys' fees incurred by Relator in the prosecution of this suit; and

HH. That Relator be granted such other and further relief as the Court deems just and proper.

### JURY TRIAL DEMAND

Relator demands a trial by jury of all issues so triable.

Dated: May 9, 2014

/s/ David W. Garrison

David W. Garrison

BARRETT JOHNSTON LLC

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### **CERTIFICATE OF SERVICE**

I hereby certify that the foregoing *First Amended Complaint for False Claims Act Violations Under 31 U.S.C. § 3729 et seq. and State Law Counterparts* has been served on the following via the Court's CM/ECF system on this the 9<sup>th</sup> day of May, 2014.

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> /s/ David W. Garrison DAVID W. GARRISON BARRETT JOHNSTON, LLC